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IN THE
# Supreme Court of the United States

BOSTON SCIENTIFIC CORPORATION
and SCIMED LIFE SYSTEMS, INC.,

*Petitioners,*

*v.*

CORDIS CORPORATION,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

I. Where the phrase "printed publication" has been continuously used in patent statutes since 1836, does the Federal Circuit's abandonment of the original construction of that phrase, refusal to apply any other plain-language construction, and substitution of its own policy goal of protecting inventors to the exclusion of Congress' goal of encouraging competition improperly alter the scope of the "loss of right to patent" provision of 35 U.S.C. § 102(b)?

II. Does the Federal Circuit's case-by-case analysis of "printed publications"—described by commentators as "a muddled mess" with "many irreconcilable conflicts"—improperly lead to an inconsistent and unpredictable scope of the "loss of right to patent" provision and frustrate Congress' policy goal of providing a bright-line on which inventors and the public can rely?

III. Does an inventor's dissemination of a printed description of his invention to commercial companies and individuals skilled and interested in the art without a legal obligation of confidentiality—for five years in an attempt to exploit his invention—bar his later attempt to file a patent application and thereby unilaterally extend the duration of his statutory monopoly and withdraw from the public domain the subject matter he had spent five years disclosing?

## CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioners Boston Scientific Corporation and Boston Scientific Scimed Inc. (formerly known as Scimed Life Systems, Inc.) state that Boston Scientific Corporation is a publicly held company and a parent corporation that owns 10 percent or more of the stock of Boston Scientific Scimed, Inc., and that no parent corporation or publicly held company owns 10 percent or more of Boston Scientific Corporation.

## TABLE OF CONTENTS

Page

QUESTIONS PRESENTED ..... i

CORPORATE DISCLOSURE STATEMENT ..... ii

TABLE OF AUTHORITIES ..... vii

INTRODUCTION ..... 1

OPINIONS BELOW ..... 4

JURISDICTION ..... 4

PERTINENT STATUTORY PROVISION ..... 4

STATEMENT OF THE CASE ..... 5

I. Background ..... 5

A. Boston Scientific's Taxus Express, Express and Liberté stents have treated millions of patients suffering from coronary artery disease. ..... 5

B. Dr. Palmaz spent five years attempting to commercially exploit his stent designs before filing for a patent application in 1985 ..... 7

C. For more than a decade, Cordis has thwarted innovation and competition by suing competitors and attempting to enjoin their products for alleged infringement of the Palmaz '762 patent ..... 9

II. Prior Proceedings ..... 10

A. The district court granted summary judgment *sua sponte* that the Palmaz Monograph was not a prior art "printed publication." ..... 10

**TABLE OF CONTENTS (cont'd)**

Page

B. The Federal Circuit affirmed the district court based on: (1) the inventor's uncorroborated litigation testimony regarding his purported subjective intent; and (2) alleged "incentives" for inventors and commercial companies exploiting inventions. ..... 11

REASONS FOR GRANTING THE WRIT ..... 12

I. The Federal Circuit's construction of "printed publication" abandons the original construction of the phrase or any other plain meaning of the terms "printed" and "publication," and frustrates the statute's policy goals. ..... 12

A. The "printed publication" bar was added to the Patent Act in 1836 to confine patent monopolies to their statutory term and to prevent the patenting of ideas in the public domain..... 12

B. As used in 1836 and today, a "printed publication" is a tangible reference capable of reproduction that has been shared with third parties without confidentiality obligations. ..... 15

C. A plain-language construction of "printed publication" comports with Congress' policy goals for the "loss of right to patent" provision..... 20

## TABLE OF CONTENTS (cont'd)

Page

D. The Federal Circuit's case-by-case application of the "printed publication" bar abandons a plain-language construction and fails to achieve the policy goals of the "loss of right to patent" statute. ..... 24

II. The Federal Circuit's application of "printed publication" has been inconsistent and sowed uncertainty, frustrating the policy goal of providing a bright-line start to competition. ..... 31

A. *Garrett Corp.*, *MIT* and their progeny equate dissemination without confidentiality obligations to "publication." ..... 32

B. *In re Wyer*, *Constant* and their progeny, however, require a case-by-case analysis that allows uncorroborated inventor testimony to salvage otherwise invalid patents. ..... 33

C. Federal Circuit dissents highlight the disagreement and confusion regarding the applicable standard. ..... 34

D. District court caselaw further highlights the inconsistent construction of "printed publication" in patent cases. .... 35

**TABLE OF CONTENTS (cont'd)**

Page

III. The Federal Circuit's decision in this case is internally inconsistent and fails to apply controlling precedent. ..... 36

A. The Federal Circuit improperly relied on Dr. Palmaz's uncorroborated litigation testimony regarding his purported subjective intent. ..... 38

B. The Federal Circuit erred in evaluating purported incentives for inventors and the Monograph recipients. ..... 39

CONCLUSION ..... 41

**APPENDIX CONTENTS**

Federal Circuit Opinion, March 31, 2009 ..... 1a

District Court Summary Judgment Order, June 5, 2005 ..... 44a

District Court Memorandum Opinion, June 5, 2005 ..... 46a

Federal Circuit Order Denying Petition For Rehearing And Petition For Reharing *En Banc*, June 26, 2009. ..... 64a

# TABLE OF AUTHORITIES

Page(s)

**Cases**

*Ajinomoto Co. v. Archer-Daniels-Midland Co.*,
No. 95-218-SLR, 1998 WL 151411
(D. Del. Mar. 13, 1998) ..... 36

*Am. Seating Co. v. USSC Group*,
514 F.3d 1262 (Fed. Cir. 2008) ..... 22

*Bate Refrigerating Co. v. Sulzberger*,
157 U.S. 1 (1895) ..... 13, 30

*Bennett Regulator Guards, Inc. v.*
*Canadian Meter Co.*,
184 Fed. Appx. 977
(Fed. Cir. 2006) ..... 34

*Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*,
489 U.S. 141 (1989) ..... 12, 13, 14, 21

*Bradford Co. v. Afco Mfg.*,
No. 1:05-cv-449, 2008 WL 570963
(S.D. Ohio Feb. 28, 2008) ..... 36

*Bruckelmyer v. Ground Heaters, Inc.*,
453 F.3d 1352 (Fed. Cir. 2006) ..... 15, 29, 35

*Burton v. Burton*,
3 Greene 316, 1851 WL 149 (Iowa 1851) .... 17

*Cohn v. U.S. Corset Co.*,
93 U.S. 366 (1876) ..... 16

**TABLE OF AUTHORITIES (cont'd)**

Page(s)

*Consol. Fruit-Jar Co. v. Wright*,
94 U.S. 92 (1876)..... 23

*Constant v. Advanced Micro-Devices, Inc.*,
848 F.2d 1560 (Fed. Cir. 1988).. 11, 26, 27, 32

*Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*,
291 F.3d 1317 (Fed. Cir. 2002)..... 33, 36

*Corona Cord Tire Co. v. Dovan Chem. Corp.*,
276 U.S. 358 (1928)..... 15, 16

*DL Res., Inc. v. FirstEnergy Solutions Corp.*,
506 F.3d 209 (3d Cir. 2007)..... 39

*Downton v. Yaeger Milling Co.*,
108 U.S. 466 (1883)..... 16

*Eames v. Andrews*,
122 U.S. 40 (1887)..... 16

*Egbert v. Lippmann*,
104 U.S. 333 (1881)..... 19, 22, 23

*Elec. Storage Battery Co. v. Shimadzu*,
307 U.S. 5 (1939)..... 13, 21

*Garrett Corp. v. United States*,
422 F.2d 874 (Ct. Cl. 1970)..... 32, 33, 34, 36

*Graham v. John Deere Co.*,
383 U.S. 1 (1966)..... 13, 14

**TABLE OF AUTHORITIES (cont'd)**

Page(s)

*Gulliksen v. Halberg*,
75 U.S.P.Q. 252 (Bd. App. 1937) ..... 15

*Hadden v. Collector*,
72 U.S. 107 (1866)..... 30

*Hill v. Scranton*,
411 F.3d 118 (3d Cir. 2005)..... 38

*I.C.E. Corp. v. Armco Steel Corp.*,
250 F. Supp. 738 (S.D.N.Y. 1966) ... 20, 24, 25

*In re Cronyn*,
890 F.2d 1158 (Fed. Cir. 1989)..... 27, 34

*In re Hall*,
781 F.2d 897 (Fed. Cir. 1986)..... 16

*In re Klopfenstein*,
380 F.3d 1345 (Fed. Cir. 2004)..... 28, 32

*In re Natures Remedies, Ltd.*
No. 2008-1436, 2009 WL 615841
(Fed. Cir. Mar. 12, 2009) ..... 33

*In re Tenney*,
254 F.2d 619 (C.C.P.A. 1958) ..... 15, 20, 29

*In re Wyer*,
655 F.2d 221 (C.C.P.A. 1981) ..... passim

*Invitrogen Corp. v. Clontech Labs., Inc.*,
429 F.3d 1052 (Fed. Cir. 2005)..... 39

**TABLE OF AUTHORITIES (cont'd)**

Page(s)

*Jursich v. J.I. Case Co.*,
350 F. Supp. 1125 (N.D. Ill. 1972) ..... 18

*Kyocera Wireless Corp. v. ITC*,
545 F.3d 1340 (Fed. Cir. 2008) ..... 33

*Lucent Techs., Inc. v. Gateway, Inc.*,
No. 02-cv-2060-B, 2007 WL 1877983
(S.D. Cal. June 27, 2007) ..... 36

*Manning v. Cape Ann Isinglass & Glue Co.*,
108 U.S. 462 (1883) ..... 21

*Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*,
153 F.2d 516 (2d Cir. 1946) ..... 21

*MIT v. AB Fortia*,
774 F.2d 1104 (Fed. Cir. 1985) .. 32, 33, 34, 36

*Northern Telecom, Inc. v. Datapoint Corp.*,
908 F.2d 931 (Fed. Cir. 1990) ..... 32

*OKI Am., Inc. v. Advanced Micro Devices, Inc.*,
No. C04-03171 CRB, 2006 WL 2711555
(N.D. Cal. 2006) ..... 35

*Pfaff v. Wells Elecs., Inc.*,
525 U.S. 55 (1998) ..... passim

*Pickering v. Holman*,
459 F.2d 403 (9th Cir. 1972) ..... 17, 20

*Rosenwasser v. Berry*,
129 U.S. 47 (1889) ..... 16

**TABLE OF AUTHORITIES (cont'd)**

Page(s)

*Seymour v. Osborne*,
78 U.S. 516 (1870) ..... 16

*Smith & Griggs Mfg. Co. v. Sprague*,
123 U.S. 249 (1887) ..... 19, 23

*SPX Corp. v. Bartec USA, LLC*,
No. 06-cv-14888, 2008 WL 1701641
(E.D. Mich. Apr. 10, 2008) ..... 36

*SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*,
511 F.3d 1186 (Fed. Cir. 2008) ..... 35

*Stevenson v. Oceanic Bank*,
223 Cal. App. 3d 306
(Cal. Ct. App. 1990) ..... 38

*Thacher v. Falmouth*,
235 F. 151 (D. Me. 1916) ..... 17

*Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*,
443 F. Supp. 2d 836 (S.D. Tex. 2006) ..... 35

*Vetco Offshore Indus., Inc. v. Rucker Co.*,
448 F. Supp. 1203 (N.D. Cal. 1978) ..... 18

**Statutes**

28 U.S.C. § 1254(1) ..... 4

35 U.S.C. § 102 ..... passim

35 U.S.C. § 154 ..... 9

**TABLE OF AUTHORITIES (cont'd)**

Page(s)

Patent Act of 1836, 5 Stat. 117, c. 357 (1836) ..... 14

**Treatises**

1-3 Donald S. Chisum, *Chisum on Patents* (2009)..... 15, 31

Wesley Kobylak, Annotation, *35 U.S.C.A. § 102(a) and (b)*, 70 A.L.R. Fed. 796 (1984, updated 2009) ..... 31

**Constitutional Provisions**

Const. Art. I, § 8, cl. 8..... 12

**Other Authorities**

John E. Vick, *Publish and Perish: The Printed Publication As A Bar to Patentability*, 18 AIPLA Q. J. 235 (1990) ... 31

Merriam-Webster's Dictionary of Law (1996)..... 18

Noah Webster, An American Dictionary of the English Language (13th ed. 1834) ..... 17

Thomas Potts, A Compendious Law Dictionary (1815)..... 17

## INTRODUCTION

Since 1836, the United States patent laws have required inventors to file patent applications within a limited time after they begin to exploit their inventions, or else suffer abandonment of their inventions to the public domain. The policy behind these statutory "loss of right to patent" provisions is simple—patents represent a carefully crafted balance between temporally-limited monopolies granted in exchange for public disclosure of inventions; requiring timely patent applications ensures that inventors do not unilaterally extend the temporal scope of their eventual monopoly, or monopolize information already released into the public domain. For almost 200 years, the triggering events for these "loss of right to patent" provisions have included sales or public uses of an invention, as well as disclosure of an invention in a "printed publication."

This petition arises from the Federal Circuit's construction and application of the "printed publication" bar to patentability. As enacted, the bar encompasses material in a sufficiently tangible form for distribution and copying, *i.e.*, "printed," that has been shared with third-parties without any confidentiality or privacy restrictions, *i.e.*, "published." It was Congress' judgment that material both "printed" and "published" had entered the public domain and/or been sufficiently exploited by the inventor that, absent a timely patent application, it should not be subject to a patent monopoly. This construction comports with the plain language of the provision, and is effective to achieve the policy goals underlying the statute.

The Federal Circuit's precedent, however, has expressly abandoned this straightforward interpretation of the statute and does not even purport to given the term "printed publication" its plain meaning. Rather, that court has substituted an amorphous pro-patentee approach – ostensibly a case-by-case "public accessibility" analysis—that allows an inventor's trial testimony regarding his purported subjective intent to salvage an otherwise invalid patent. There is no basis for this approach, which contradicts the plain language and frustrates the policy goals of the statute. It is improper, and warrants review and reversal.

The Federal Circuit's case-by-case approach has engendered disputes and sown confusion regarding the applicable standard to apply. Courts have evidenced this uncertainty through conflicting analyses and results. Commentators have characterized this area of law as "a muddled mess" and "anomalous, with many irreconcilable conflicts." This has further frustrated the policy goal of providing a bright-line on which inventors, competitors and the public can rely. For this reason as well, the Federal Circuit's construction and application of "printed publication" is improper and warrants reversal.

The flaws in the Federal Circuit's approach are highlighted in this case. Dr. Julio Palmaz wrote a Monograph describing his invention in 1980. For five years, he attempted to exploit his invention by disseminating copies of this Monograph to commercial companies and persons of skill and interest in the art. No confidentiality obligations controlled this dissemination. In fact, contracts with

the commercial companies explicitly disavowed any such restrictions. Only five years later did he file a patent application, and thereby start the process for obtaining his monopoly period. The Monograph was "printed" and a "publication," and should have invalidated the untimely patent.

Rather than apply the bright-line statutory provision, the Federal Circuit relied on Dr. Palmaz's purported subjective intent—unknown and unknowable until Dr. Palmaz's uncorroborated litigation testimony decades later—to hold that the Monograph was somehow not a "printed publication." And the court explicitly applied its own policy analysis—regarding the purported incentives for inventors and commercial companies—to the exclusion of the policies underlying the "loss of right to patent" provision. This improperly ignored the historic construction, plain language and policies of the statute.

As a result of the Federal Circuit's ruling, Dr. Palmaz's patent was found not invalid. Cordis Corporation—the assignee of Dr. Palmaz's patent—spent more than a decade arguing that the Palmaz patent prohibited any company from designing or offering competing products, and seeking to enjoin all competition through lawsuits. If the "printed publication" statute had been properly applied, the Palmaz patent would have been invalid *ab initio* and Cordis' competitors would have been spared Cordis' decade of litigation. And in this case, Cordis is seeking *billions* of dollars in purported damages for Boston Scientific's sale of medical devices from 2003-2005. If Dr. Palmaz had timely filed a patent application by 1981, his patent would have expired

well before 2003, and Boston Scientific's liability for sales from 2003-2005 would be *zero*. The magnitude and inequity of this result warrants review and reversal.

## OPINIONS BELOW

The district court's *sua sponte* summary judgment that the Monograph was not a "printed publication" under 35 U.S.C. § 102(b) is reprinted in the Appendix ("App.") at 44a-63a. The Federal Circuit's decision affirming the district court is reported at 561 F.3d 1319 and is reproduced in the Appendix at 1a-43a.

## JURISDICTION

The Federal Circuit rendered its decision on March 31, 2009, App. 1a-43a, and denied a timely petition for rehearing on June 26, 2009, App. 64a-65a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## PERTINENT STATUTORY PROVISION

35 U.S.C. § 102 provides in relevant part:

> **Conditions for patentability; novelty and loss of right to patent**
>
> A person shall be entitled to a patent unless—
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States

## STATEMENT OF THE CASE

At issue in this case is the statutory construction of the phrase "printed publication." As enacted in 1836, and as a matter of plain English today, the phrase refers to material that has been "printed"—*i.e.*, in a sufficiently tangible form to be copied and shared—and "published"—*i.e.*, disseminated to third-parties without any obligation of confidentiality. The Federal Circuit, however, has expressly abandoned this plain-language construction in favor of a case-by-case analysis that considers the inventor's subjective intent in exploiting his or her invention. In this case, that approach has allowed Cordis to stifle competition and attempt to enjoin every major competitor for twenty-five years after Dr. Palmaz's invention was ready for patenting. And it has allowed Cordis to seek billions of dollars from Boston Scientific for alleged infringement that occurred years after the patent would have expired if timely filed.

### I. Background

#### A. Boston Scientific's Taxus Express, Express and Liberté stents have treated millions of patients suffering from coronary artery disease.

Petitioner Boston Scientific is a world-wide leader in the design and development of stents for the treatment of coronary artery disease. Coronary artery disease can result from a build-up of plaque in a patient's blood vessels, constricting the blood flow reaching the heart's muscle tissue. This can lead to chest pain, shortness of breath and--in extreme presentations—heart attack and even death.

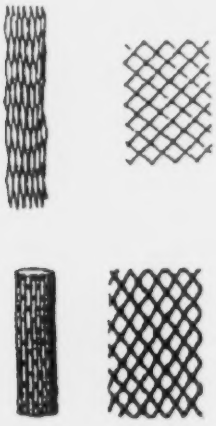
Balloon angioplasty has been used for decades to treat coronary artery disease. A catheter is inserted into a relatively non-invasive entry site—such as the femoral artery in the leg—and threaded through the patient's vasculature to the site of blockage. A balloon on the catheter is then inflated, compressing the plaque against the vessel wall to reopen the blood vessel. The balloon catheter is then deflated and removed. This offers a faster and much less invasive option than coronary artery bypass surgery, one of the few alternative treatments previously available.

Stents are metal scaffolds delivered in conjunction with balloon angioplasty. When the balloon expands, the scaffold also expands to provide a mechanical support inside the blood vessel. This prevents blood vessels from elastically re-narrowing once the balloon is removed, and also prevents loosened plaque from blocking blood flow. Boston Scientific's Express and Liberté bare-metal stents, launched in the United States in 2002 and 2005, respectively, have been used to treat millions of patients suffering from coronary artery disease.

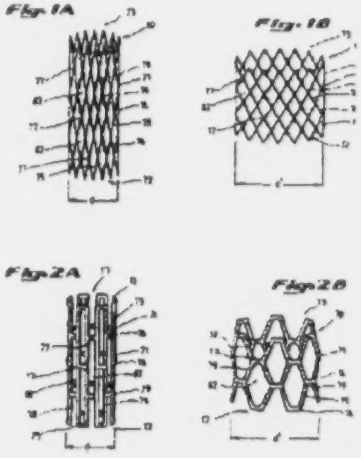
Drug-eluting stents combine this mechanical support with a pharmacological agent aimed at slowing the re-closure, called restenosis, of the previously blocked artery. This has greatly improved the efficacy of stenting procedures, and expanded the range of lesions that physicians can treat. Because of such improvements in outcomes, Boston Scientific has sold many billions of dollars worth of its drug-eluting Taxus Express stent since it was launched in the United States in 2004.

### B. Dr. Palmaz spent five years attempting to commercially exploit his stent designs before filing for a patent application in 1985.

In 1980, Dr. Palmaz authored a monograph disclosing his balloon-expandable stent designs. As shown below, the figures disclosing these stent designs were virtually identical to those of Dr. Palmaz's 1985-filed patent application:



(Figures from 1980 Monograph)



(Figures from patent application)

For the next five years, Dr. Palmaz attempted to commercialize his invention. As the Federal Circuit summarized:

> In 1980 the inventor of the '762 patent, Dr. Palmaz, prepared a ten-page paper describing his work on stents ["the Monograph"]. . . . He gave copies of the paper to approximately six of his teachers . . . and several other colleagues. Pursuant to agreements, Palmaz later gave copies of the monograph to two companies (Vascor, Inc., and Shiley, Inc.)

> while attempting to commercialize his stent technology. Neither agreement required confidentiality. . . . Dr. Palmaz applied for the patent that became the '762 patent in 1985.

App. 26a-27a (footnotes omitted). A revised version of the Monograph was disseminated in 1983 to at least three additional individuals and two university committees. This list of recipients of the Monograph is not exhaustive, but the district court's *sua sponte* summary judgment on this issue restricts the scope of the record on appeal.

There were no confidentiality agreements, no evidence from the recipients of the Monograph of any confidentiality obligations, and no confidentiality notices in the Monograph itself. App. 26a-27a. Dr. Palmaz's contract with Vascor, Inc. was a sale of "all . . . present and future right, title and interest" in his invention, and allowed Vascor to exploit the monograph however it saw fit. Dr. Palmaz's contract with Shiley similarly stated that:

> All material shall be considered as having been submitted without any requirements of confidence on the part of the Company, and no confidential relationship, express or implied, shall be established between the Company and the submitter in respect to such material.

Dr. Palmaz did not file the patent application that led to the patent-in-suit until 1985.

### C. For more than a decade, Cordis has thwarted innovation and competition by suing competitors and attempting to enjoin their products for alleged infringement of the Palmaz '762 patent.

Respondent Cordis subsequently acquired the '762 patent and began filing lawsuits against all of the major manufacturers in the stent industry. For more than a decade, Cordis has pursued these litigations in an effort to enjoin its competitors and extract purported lost profits and royalties. Cordis has repeatedly argued that the Palmaz '762 patent blocks all competition in balloon-expandable stents, and that no competitors can develop or offer new products to treat coronary artery disease without being threatened by Cordis' patent monopoly.

Cordis filed suit against Boston Scientific on January 13, 2003—twenty-three years after Dr. Palmaz began to commercially exploit his invention. In this case, Cordis seeks billions of dollars in purported damages from Boston Scientific for sales of drug-eluting and bare-metal stents from 2003-2005. If Dr. Palmaz had filed for his patent within one year of beginning his commercial exploitation, *i.e.*, by 1981, his patent would have expired long before 2003. 35 U.S.C. § 154.

## II. Prior Proceedings

### A. The district court granted summary judgment *sua sponte* that the Palmaz Monograph was not a prior art "printed publication."

Cordis filed its complaint against Boston Scientific on January 13, 2003 claiming, *inter alia*, alleged infringement of the '762 patent. On March 24, 2005, Boston Scientific moved for summary judgment that the '762 patent was invalid in light of the Monograph. Although neither briefed nor raised by either party, the district court *sua sponte* granted summary judgment that the Monograph was *not* a "printed publication" and barred Boston Scientific from raising a "printed publication" defense at trial.[1]

Cordis' claims were tried in June 2005 and Boston Scientific's Taxus Express, Express and Liberté stents were found to infringe Claims 1 and 23 of the '762 patent.

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[1] For one of the two claims of the '762 patent asserted at trial, the district court additionally barred Boston Scientific's invalidity defense due to the purported collateral estoppel effects of co-pending litigation. However, the Federal Circuit did not address that issue in light of its holding regarding the "printed publication" question. App. 31a n.13.

### B. The Federal Circuit affirmed the district court based on: (1) the inventor's uncorroborated litigation testimony regarding his purported subjective intent; and (2) alleged "incentives" for inventors and commercial companies exploiting inventions.

On October 17, 2007, Boston Scientific appealed, *inter alia*, the judgment that Claims 1 and 23 of the '762 patent were not invalid in light of the Monograph. As phrased by the Federal Circuit, the relevant issue on appeal was "whether the distribution to a limited number of entities without a legal obligation of confidentiality renders the monographs printed publications under §102(b)." App. 28a. In analyzing this question, the Federal Circuit recognized that these distributions represented Dr. Palmaz's attempt to commercialize his invention, and that binding contracts exempted the commercial recipients of the Monograph from any legal obligation of confidentiality. App. 26a-27a.

Citing *In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981), and *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988), the court applied a "public accessibility test" to evaluate the Monograph—rather than ascertaining whether the Monograph was "printed" or a "publication"—and held that the Monograph was not "publicly accessible" in light of: (1) Dr. Palmaz's uncorroborated litigation testimony regarding his purported subjective intent in disseminating the Monograph; and (2) alleged "incentives" for inventors and commercial companies exploiting inventions.

App. 25a-31a. As a result, on March 31, 2009, the appellate panel affirmed the district court's *sua sponte* summary judgment that the Monograph was not a "printed publication." App. 31a.

Boston Scientific timely filed a petition for panel rehearing or rehearing *en banc*, which was denied on June 26, 2009. App. 64a-65a.

## REASONS FOR GRANTING THE WRIT

### I. The Federal Circuit's construction of "printed publication" abandons the original construction of the phrase or any other plain meaning of the terms "printed" and "publication," and frustrates the statute's policy goals.

#### A. The "printed publication" bar was added to the Patent Act in 1836 to confine patent monopolies to their statutory term and to prevent the patenting of ideas in the public domain.

The United States Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing *for limited Times* to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Const. Art. I, § 8, cl. 8 (emphasis added). "The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 145 (1989).

The federal patent laws have been designed to implement this desired balance. "The inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent." *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966). "[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) (citing *Bonito Boats*, 489 U.S. at 151).

From the first Patent Act in 1790, this mandate manifested itself as a requirement that patents only be granted on "any useful art, manufacture, engine, machine, or device, or any improvement therein '*not before known or used.*'" *Bate Refrigerating Co. v. Sulzberger*, 157 U.S. 1, 19-20 (1895) (emphasis added). In contrast, technology that was before known or used—*i.e.*, "prior art"—would operate to bar subsequent patents. This conception of prior art, as knowledge known or used by others, was repeated with minor clarifying changes in the 1793 and 1800 Patent Acts. *Id.* at 20-21.

The Patent Act of 1836, however, redefined the content of the prior art. In addition to knowledge "known or used by others before [the patentee's] discovery or invention," the 1836 Act added art "in public use or on sale, with [the patentee's] consent or allowance" and art "described . . . in any printed publication." *Id.* at 21; *see also Elec. Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 9-14 (1939) (recounting the history of the patent acts). For the first time, an inventor's own actions in exploiting his or her

invention could bar a later application for a patent. Such "loss of right to patent" provisions were designed "as a limiting provision, both excluding ideas in the public domain from patent protection and confining the duration of the monopoly to the statutory term." *Pfaff*, 525 U.S. at 64 (discussing 35 U.S.C. §102).

With minor modifications—such as the duration of the grace period for filing a patent application after a triggering sale, use or publication—today's "loss of right to patent" provision has descended largely unchanged from its original formulation. *Compare*, Patent Act of 1836, 5 Stat. 117, c. 357 (1836) *with* 35 U.S.C. §102(b); *see also Graham*, 383 U.S. at 12 (tracing the origins of §102 of the 1952 Patent Act through the 1874 statutory scheme). These two conceptions of prior art—as prior inventions by others and as inventions previously exploited by the patentee—are now formally enumerated in 35 U.S.C. §§ 102(a) and 102(b), respectively. *See Bonito Boats*, 489 U.S. at 148 ("Sections 102(a) and 102(b) operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public.").

### B. As used in 1836 and today, a "printed publication" is a tangible reference capable of reproduction that has been shared with third parties without confidentiality obligations.

#### *(i) "Printed" material is sufficiently tangible so as to be shared and copied.*

As originally enacted, the "printed" requirement of "printed publication" limited the phrase to material sufficiently tangible so as to allow sharing and copying. *See, e.g., Corona Cord Tire Co. v. Dovan Chem. Corp.*, 276 U.S. 358, 372-73 (1928) (finding that an oral presentation was not "printed" and therefore could not comprise a "printed publication"); *Gulliksen v. Halberg*, 75 U.S.P.Q. 252, 253 (Bd. App. 1937) (noting that "printed" was meant to distinguish fixed text from fleeting means that might be published, such as gestures or lectures); *Bruckelmyer v. Ground Heaters, Inc.*, 453 F.3d 1352, 1354 (Fed. Cir. 2006) (Newman, J., dissenting) ("[I]n the case of 'printed' publications, Congress no doubt reasoned that one would not go to the trouble of printing a given description of a thing unless it was desired to print a number of copies of it.").

While some courts initially applied a narrow reading to "printed," *see, e.g., In re Tenney*, 254 F.2d 619, 625 (C.C.P.A. 1958) (noting that a purely handwritten document could never comprise a "printed publication"), "[t]he trend of court decisions has been toward a broad interpretation of 'printed' that encompasses all material available to the public in a tangible form." 1-3 Donald S. Chisum, *Chisum*

*on Patents* § 3.04[3] (2009) (emphasis added). Rather than limiting the statutory phrase to movable type, courts have recognized that other media can properly be deemed "printed." *See, e.g.*, *In re Hall*, 781 F.2d 897, 898 (Fed. Cir. 1986) ("The statutory phrase 'printed publication' has been interpreted to give effect to ongoing advances in the technologies of data storage, retrieval, and dissemination."); *Wyer*, 655 F.2d at 225-27 (holding that microfilm could qualify as a "printed publication"). The key factor is sufficient tangibility for dissemination and reproduction.

*(ii) A "publication" is material shared with third parties without any confidentiality obligation.*

Early caselaw applying the bar construed "printed publication" in a literal sense—"publication" was a discrete event that would transform "printed" material into prior art. *See, e.g.*, *Seymour v. Osborne*, 78 U.S. 516, 555 (1870) (discussing "the particular circumstances under which the publication takes place"); *Cohn v. U.S. Corset Co.*, 93 U.S. 366, 370 (1876) (discussing "the earlier printed and published description"); *Downton v. Yaeger Milling Co.*, 108 U.S. 466, 471 (1883) (noting the date and location of publication for a prior art reference); *Eames v. Andrews*, 122 U.S. 40, 64-65 (1887) (same); *Rosenwasser v. Berry*, 129 U.S. 47, 50 (1889) (same); *Corona Cord Tire Co.*, 276 U.S. at 371-373 (distinguishing between the oral reading of a paper and its later "publication" in "printed" form).

At the time of enactment in 1836, the term "publication," as well as the act of "publishing," referred to dissemination to third parties without

obligations of confidentiality. This was true for legal usage: "*[P]ublication*: which is a power to shew the depositions openly, and to give out copies of them." Thomas Potts, A Compendious Law Dictionary 558 (1815). And this was also reflected in the more general usage of the term in American parlance:

> Publication: 1. The act of publishing or offering to public notice . . .
>
> Publish: 1. To discover or make known to mankind or to people in general what before was private or unknown; to divulge, as a private transaction; to promulgate or proclaim, as a law or edict. 2. To send a book into the world; or to sell or offer for sale a book, map or print. 3. To utter; to put off or into circulation . . .

Noah Webster, An American Dictionary of the English Language 653 (13th ed. 1834). Caselaw of the era further confirms this understanding of "publication." *See, e.g.*, *Burton v. Burton*, 3 Greene 316, 1851 WL 149, *3 (Iowa 1851) ("Publishing is defined, by an able lexicographer, to be, 'making known, divulging, proclaiming' . . . the additional allegation that the words were published in the presence of divers persons, would have been surplusage.").

And more modern caselaw continued this definition. *See, e.g.*, *Thacher v. Falmouth*, 235 F. 151, 153 (D. Me. 1916), *aff'd*, 241 F. 869 (1st Cir. 1917) (equating "publication" with distribution to any part of the public without an injunction of secrecy); *Pickering v. Holman*, 459 F.2d 403, 407 (9th Cir. 1972) ("Any publication, regardless of the purposes behind it, violates the policies behind the

publication bar."); *Vetco Offshore Indus., Inc. v. Rucker Co.*, 448 F. Supp. 1203, 1208-10 (N.D. Cal. 1978) (holding that the display of a printed document constituted "publication" where no confidentiality obligations existed); *Jursich v. J.I. Case Co.*, 350 F. Supp. 1125, 1128 (N.D. Ill. 1972), *aff'd sub nom. Jursich v. Case Co.*, 487 F.2d 1404 (7th Cir. 1973) (finding a report to constitute a "printed publication" where it was distributed to commercial entities without confidentiality obligations). This understanding of the caselaw is mirrored in modern dictionaries:

> Publication: 1. the act or process of publishing; 2. a published work . . .
>
> Publish: 1. to make known to another or to the public generally—For purposes of defamation, a defamatory communication made to only one third party may be considered published. . . . 3a: to disseminate to the public or provide notice of to the public or to an individual . . .

Merriam-Webster's Dictionary of Law 395, 397 (1996). Material shared with any third-party, without an obligation of confidentiality, is a "publication" under the 1836 definition of the term as well as its usage today.

*(iii) A "printed publication" is any tangible material capable of dissemination and copying which is shared with third parties without any confidentiality obligation.*

Because "publication" could occur in many forms, *e.g.*, physical, verbal, visual, etc., the term operated in conjunction with the "printed" requirement to ensure that the statute covered lasting disclosures without confidentiality obligations, rather than fleeting demonstrations. Congress deemed such "printed publications" sufficiently in the public domain and/or sufficiently exploited by the inventor so as to bar later withdrawal of any disclosed inventions into a patent monopoly, unless an application was timely filed. *See Pfaff*, 525 U.S. at 64 ("§102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term.").

Rather than a case-by-case inquiry, Congress chose to implement bright-line provisions in § 102(b). A single sale would invalidate a patent filed more than one year thereafter. *See Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887) ("A single sale . . . would certainly have defeated his right to a patent"); *Pfaff*, 525 U.S. at 64. A single public use would also invalidate such a patent. *Egbert v. Lippmann*, 104 U.S. 333 (1881). And a single "printed publication" should be no different:

> [O]nce it has been established that the item has been both printed and published, it is not necessary to further show that any given

> number of people actually saw it or that any specific number of copies have been circulated. *The law sets up a conclusive presumption to the effect that the public has knowledge of the publication when a single printed copy is proved to have been so published.*

*Tenney*, 254 F.2d at 626-27 (emphasis added). This understanding was echoed by other appellate and district courts:

> Anything that is printed and made accessible to any part of the public is a printed publication. . . . The publication bar goes upon the theory that the idea is already in the public domain and there can be no consideration offered in exchange for the grant of the monopoly.

*Pickering*, 459 F.2d at 407; *see also I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 740-41 (S.D.N.Y. 1966) (noting that when the term "printed publication" was added in 1836, "a 'printed publication' was considered 'broad enough to include any description printed in any form and published or circulated to any extent'"). This was the balance Congress struck, as well as the plain meaning of the terms it chose to employ.

### C. A plain-language construction of "printed publication" comports with Congress' policy goals for the "loss of right to patent" provision.

The Congressional intent behind the "loss of right to patent" provision remains the same as in 1836: "Once an inventor has decided to lift the veil of secrecy from his work, he must choose the protection

of a federal patent or the dedication of his idea to the public at large." *Bonito Boats*, 489 U.S. at 149. "[I]t is a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly." *Id.* (citing *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946)).

In applying the "on-sale" and "public use" bars, two factors have played a prominent role: (1) distinguishing confidential from non-confidential acts; and (2) applying a bright-line rule. These factors comport with the policy goals underlying the "loss of right to patent" provision—providing a clear trigger that inventors can control and the public can rely on, and preventing inventors from removing their inventions from the public domain or otherwise temporally extending the statutory patent monopoly.

*(i) The existence or absence of confidentiality obligations controls the § 102(b) analysis for inventions "on-sale" or in "public use."*

Courts applying § 102(b), and its predecessor statutes, have emphasized that the key determination is the existence or absence of confidentiality obligations. *See, e.g.*, *Manning v. Cape Ann Isinglass & Glue Co.*, 108 U.S. 462, 465 (1883) ("Norwood and his son were allowed by the inventor the unrestricted use of the patent during the period mentioned, without injunction of secrecy or other condition. This is sufficient to constitute a public use."); *Elec. Storage Battery Co.*, 307 U.S. at 20 ("A mere experimental use is not the public use

defined by the Act, but a single use for profit, not purposely hidden, is such."); *Am. Seating Co. v. USSC Group*, 514 F.3d 1262, 1267 (Fed. Cir. 2008) ("An invention is in public use if it is shown to or used by an individual other than the inventor under no limitation, restriction, or obligation of confidentiality."). As expressed by this Court over a century ago:

> [W]hether the use of an invention is public or private does not necessarily depend upon the number of persons to whom its use is known. If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public, even though the use and knowledge of the use may be confined to one person.

*Egbert*, 104 U.S. at 336. The existence or lack of confidentiality obligations is the key inquiry.

*(ii) The § 102(b) analysis for inventions "on-sale" or in "public use" provides a bright-line for inventors and the public.*

Rather than promulgate a case-by-case analysis for § 102(b), Congress enacted bright-line triggers. "[T]hese provisions identify an interest in providing inventors with a definite standard for determining when a patent application must be filed." *Pfaff*, 525 U.S. at 65. Such bright-lines impose no undue burdens, as "[a]n inventor can both understand and control the timing of the first commercial marketing of his invention." *Id.* at 67.

Thus, a single "sale" or "public use" triggers § 102(b), regardless of whether the invention is publicly accessible or otherwise widely in the public domain. *See Smith*, 123 U.S. at 257 ("A single sale . . . would certainly have defeated his right to a patent."); *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1876); *Pfaff*, 525 U.S. at 67. As stated by the Court:

> [O]ne well-defined case of [public] use is just as effectual to annul the patent as many. . . . [I]f the inventor . . . makes and sells only one of the articles invented by him . . . without restriction or limitation, the use is just as public as if he had sold and allowed the use of a great number.

*Egbert* 104 U.S. at 336 (internal citations omitted). As shown by this Court's decisions, a bright-line approach controls the § 102(b) analysis.

*(iii) A plain-language construction of "printed publication" properly maintains a focus on the existence or absence of confidentiality obligations and provides a bright-line for inventors and the public.*

The plain-language construction of "printed publication"—as tangible material disseminated without confidentiality obligations—comports with the policy goals and other triggers of § 102(b). It provides a bright-line which inventors can control and on which the public can rely. And it prevents inventors from exploiting their inventions for years, only to later file a patent application and thereby start the process for obtaining their monopoly. As discussed below, the Federal Circuit's abandonment

of this plain-language application of "printed publication" has stripped the power of § 102(b) to achieve the policy goals underlying its enactment.

### D. The Federal Circuit's case-by-case application of the "printed publication" bar abandons a plain-language construction and fails to achieve the policy goals of the "loss of right to patent" statute.

As reflected in the panel's decision, the Federal Circuit's new standard for evaluating "printed publications" involves a case-by-case analysis designed to maintain purported incentives for inventors to exploit their inventions. It can turn on an inventor's uncorroborated litigation testimony regarding his or her purported subjective intent. Whether material is either "printed" or a "publication" is no longer relevant under this approach, and the "printed publication" bar is no longer a bright-line.

#### *(i) The "unitary concept" of Wyer abrogated the original construction of "printed publication" and disavowed consideration of whether material was either "printed" or a "publication."*

The Federal Circuit's departure from a plain-language construction of "printed publication" can be traced to a 1966 district court opinion from the Southern District of New York. In *I.C.E. Corp.*, the district court analyzed the policy goals of the "printed publication" provision. Reasoning that the policy was to exclude material already accessible to

the public, the district court concluded that "printed publications" could include media not known in 1836:

> After reviewing the cases in this area, it might be said that the term "printed publication" as contemplated by Congress in 35 U.S.C. 102 can include a document printed, reproduced or duplicated by modern day methods, including microfilming, upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that person interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation.

*I.C.E. Corp.*, 250 F. Supp. at 743.

While *I.C.E. Corp.* sought to augment § 102(b) to account for new media not available in 1836, the Court of Customs and Patent Appeals—a court whose precedent the Federal Circuit adopted as controlling—seized upon this language to reformulate the "printed publication" analysis in *In re Wyer*. First, the court formally severed ties with any plain-meaning application of "printed publication"—*i.e.*, as material both "printed" and "published"—and instead promulgated a "unitary concept." *Wyer*, 655 F.2d at 226. And second, the court defined this "unitary concept" with the accessibility dicta of *I.C.E. Corp.*; what had been offered to augment the plain-language construction was now used to replace that construction. *Id.* at 226 (citing *I.C.E. Corp.*, 250 F. Supp. at 743). No longer was any "publication" sufficient, but only publication

that the court deemed sufficient to grant "accessibility" to the "pertinent part of the public." *Wyer*, 655 F.2d at 226.

The construction of "printed publication" offered by *Wyer* was divorced from the constituent terms "printed" and "publication." And it explicitly substituted that court's policy judgment for the prior statutory construction:

> Given the state of technology . . . the "probability of dissemination" of an item very often has little to do with whether or not it is "printed" in the sense of that word when it was introduced into the patent statutes in 1836.

*Id.* This decision replaced a bright-line rule with a court's discretion to determine whether a given inventor deserved patent protection.

*(ii) The Federal Circuit improperly adopted the "unitary concept" of Wyer to the exclusion of the 1836 construction of "printed publication" or any other consideration of whether material was "printed" or a "publication."*

Rather than adopting Congress' rule that any document that was both "printed" and "published" should serve as a bar to patentability, the Federal Circuit built on *Wyer* to institute its own case-by-case assessment of whether material was "sufficiently accessible"—in that court's opinion—to bar patentability. *See Constant*, 848 F.2d at 1568 ("The statutory phrase 'printed publication' has been interpreted to mean that before the critical date the

reference must have been sufficiently accessible to the public interested in the art."). Thus, the Federal Circuit assumed the role of determining whether a given inventor's prior exploitation of his or her invention should bar a later patent monopoly.

This shift away from a plain-language construction of "printed publication" to a case-by-case approach is illustrated in *In re Cronyn*, 890 F.2d 1158 (Fed. Cir. 1989). In that case, a thesis had been shelved in a library and indexed by the author's name, but not by subject matter. The majority of the court cited *Constant* and concluded that the thesis was not a "printed publication"—notwithstanding the fact that it was "printed" and had been disseminated to third parties without any confidentiality obligations, *i.e.*, "published"—because the thesis was somehow not "sufficiently accessible to the public interested in the art." *Id.* at 1160.

Applying a more literal construction of "publication," the dissent disagreed. *Id.* at 1161 (Mayer, J. dissenting). "Earlier decisions . . . interpreting the predecessor to section 102(b), were to the same effect: shelving a thesis in a university library is alone sufficient to render it a 'printed publication.'" *Id.* But the majority's view held the day, and a plain-meaning construction was abandoned in favor of the Federal Circuit's discretion.

The Federal Circuit's later decisions continued down this path, evaluating "printed publications" on a case-by-case basis for purported public accessibility, rather than inquiring into whether they were "printed" or a "publication," either as those terms were used in 1836 or today:

> Appellants acknowledge that our precedent considers the term "printed publication" to be a unitary concept that may not correspond exactly to what the term "printed publication" meant when it was introduced into the patent statutes in 1836. *In re Wyer*, 655 F.2d at 226. Indeed, the question to be resolved in a "printed publication" inquiry is the extent of the reference's "accessibility to at least the pertinent part of the public, of a perceptible description of the invention, in whatever form it may have been recorded." *Id.*

*In re Klopfenstein*, 380 F.3d 1345, 1348 n.2 (Fed. Cir. 2004).

The Federal Circuit has continued and compounded this approach in the present case. Although the Monograph was both "printed" and "published" five years prior to any patent application, the Federal Circuit ruled that it was not a "printed publication" based on: (1) the inventor's purported subjective intent in disseminating the Monograph; and (2) the alleged "incentives" for inventors and commercial companies exploiting inventions. In so doing, the Federal Circuit explicitly relied on its own policy considerations—*e.g.*, "preserv[ing] the incentive for inventors to participate in academic presentations or discussions"—rather than the plain language or the policy goals of the statute. App. 29a. Such an approach and purported justification evidences how far the Federal Circuit has strayed from the bright-line rule promulgated by Congress.

*(iii) The Federal Circuit's attempt to apply its own policy analysis is improper and warrants review and reversal.*

This departure from the plain language and policy of the statute was highlighted in a recent dissent, which rejected the Federal Circuit's substitution of its own policy judgment for the plain language and policy basis of the statute:

> But though the law has in mind the probability of public knowledge of the contents of the publication, the law does not go further and require that the probability must have become an actuality. In other words, once it has been established that the item has been both printed and published, it is not necessary to further show that any given number of people actually saw it or that any specific number of copies have been circulated. *The law sets up a conclusive presumption to the effect that the public has knowledge of the publication when a single printed copy is proved to have been so published.*

*Bruckelmyer*, 453 F.3d at 1354 (Newman, J., dissenting) (emphasis added) (citing *Tenney*, 254 at 626-27).

This "conclusive presumption" was the mechanism adopted by Congress for achieving the policy goals of creating a bright-line that prevented inventors from unilaterally extending their patent monopolies or otherwise withdrawing inventions from the public domain that they had been exploiting for more than one year. The Federal Circuit's abandonment of the plain language of the statute in

favor of its own policy is improper because "the [statutory] language used is so plain and unambiguous that a refusal to recognize its natural, obvious meaning would be justly regarded as indicating a purpose to change the law by judicial action based upon some supposed policy of congress." *Bate Refrigerating Co.*, 157 U.S. at 36-37.

Even if the Federal Circuit were attempting to implement the policy goals of § 102(b)—rather than the court's policy of protecting inventor incentives—it would still not justify an abandonment of the statute's plain language:

> What is termed the policy of the government with reference to any particular legislation is generally a very uncertain thing, upon which all sorts of opinions, each variant from the other, may be formed by different persons. It is a ground much too unstable upon which to rest the judgment of the court in the interpretation of statutes.

*Id.* at 37 (citing *Hadden v. Collector*, 72 U.S. 107, 111-12 (1866)). The Federal Circuit's improper approach—based on this "unstable ground"—has far-reaching effects. It implicates almost every patent where the inventor practiced or exploited his or her invention before filing a patent application. It is therefore ripe for review and properly reversed by this Court.

## II. The Federal Circuit's application of "printed publication" has been inconsistent and sowed uncertainty, frustrating the policy goal of providing a bright-line start to competition.

The Federal Circuit's departure from the plain-language construction of "printed publication" in favor of a case-by-case analysis has replaced a bright-line test with an ambiguous standard. As discussed by modern commentators: "the law construing 'printed publication' has been called a muddled mess and . . . the present law is said to be anomalous, with many irreconcilable conflicts." Wesley Kobylak, Annotation, *Meaning of the term "printed publication" under 35 U.S.C.A. § 102(a) and (b)*, 70 A.L.R. Fed. 796, § 2[a] (1984, updated 2009) (internal citations omitted); *see also* John E. Vick, *Publish and Perish: The Printed Publication As A Bar to Patentability*, 18 AIPLA Q. J. 235, 236 (1990).

This uncertainty is specifically associated with situations analogous to those presented in this case: "A distribution to a limited group with an injunction to secrecy is not a publication . . . . More difficult is the case of a limited distribution beyond a single organization where there is no express or implied injunction of secrecy." 1-3 Chisum on Patents § 3.04[2] (discussing cases). This uncertainty can be traced to two competing lines of precedent from the Federal Circuit—one following the original, plain-language construction of "printed publication" and the other adopting the court's novel case-by-case analysis.

### A. *Garrett Corp.*, *MIT* and their progeny equate dissemination without confidentiality obligations to "publication."

The Court of Claims—another court whose precedent the Federal Circuit has adopted—laid down a bright-line rule regarding "printed publications" in 1970: "While distribution to government agencies and personnel alone may not constitute publication, distribution to commercial companies without restrictions on use clearly does." *Garrett Corp. v. United States*, 422 F.2d 874, 878 (Ct. Cl. 1970) (internal citations omitted). In that case, a report disseminated to six commercial companies without any confidentiality obligation was judged a "printed publication." *Id.*

This rule was followed in a line of precedent that developed independent of the "public accessibility" test of *Wyer* and *Constant*, discussed above. For example, in *MIT v. AB Fortia*, 774 F.2d 1104, 1108-09 (Fed. Cir. 1985), a reference presented at a conference and disseminated to six individuals was held a "printed publication" based on *Garrett*. Subsequent cases clarified that the key to the holding in *MIT* was this dissemination of six copies without confidentiality obligations. *See Klopfenstein*, 380 F.3d at 1349.

Later cases confirmed that confidentiality obligations are the determinative factor for this line of precedent. *Compare Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 936 (Fed. Cir. 1990) (finding a document labeled "Reproduction or further dissemination is not authorized . . . not for public release" to not constitute a "printed publication"

despite dissemination to third parties) *with Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323-24 (Fed. Cir. 2002) (distinguishing *Northern Telecom* and finding that a reference could constitute a "printed publication" when disseminated to nine recipients who were allowed to share the information); *Kyocera Wireless Corp. v. ITC*, 545 F.3d 1340, 1350-51 (Fed. Cir. 2008) (finding that a reference shared with commercial companies could constitute a "printed publication" because there was no "veil of secrecy" and no restrictions on the recipients' further dissemination of the information); *In re Natures Remedies, Ltd.*, No. 2008-1436, 2009 WL 615841, at *5 (Fed. Cir. Mar. 12, 2009) ("The board's determination as to public accessibility, moreover, is supported by the fact that the Medi-Tab Application itself contains no restrictions on public dissemination.").

This caselaw comports with the plain-language construction of "printed publication." Under this line of precedent, the Monograph is a "printed publication" because it was disseminated without confidentiality obligations to, *inter alia*, two commercial companies as part of Dr. Palmaz's attempt to commercialize his invention.

### B. *In re Wyer, Constant* and their progeny, however, require a case-by-case analysis that allows uncorroborated inventor testimony to salvage otherwise invalid patents.

While the *Garrett Corp.* and *MIT* line of cases applied a bright-line rule, the *Wyer* and *Constant* line of cases favored a case-by-case analysis, as

discussed above. The Federal Circuit's decision in this case highlights this tension between the two lines of precedent. The court relied on Dr. Palmaz's purported subjective intent in exploiting his invention from 1980-85, and the alleged incentives for Dr. Palmaz and the Monograph recipients, to find the Monographs not sufficiently "publicly accessible" to justify barring a later patent. Such reliance on the uncorroborated subjective intent of the inventor—unknowable to the public until his litigation testimony—highlights the conflict between the Federal Circuit's two lines of precedent. And it troublingly erases any bright-line on which inventors or the public can rely, while empowering courts to redefine the scope of prior art on a case-by-case basis. It fundamentally conflicts with *Garrett* and *MIT*, and creates a "muddled mess" for courts judging printed publications.

### C. Federal Circuit dissents highlight the disagreement and confusion regarding the applicable standard.

Since the Federal Circuit first applied its "public accessibility" framework, dissents have noted the departure from the original bright-line rule that governed the "printed publication" analysis. *See, e.g.*, *Cronyn*, 890 F.2d at 1161 (Mayer, J., dissenting) ("Earlier decisions . . . interpreting the predecessor to section 102(b), were to the same effect: shelving a thesis in a university library is alone sufficient to render it a 'printed publication.'"); *Bennett Regulator Guards, Inc. v. Canadian Meter Co.*, 184 Fed. Appx. 977, 982-983 (Fed. Cir. 2006) (Mayer, J., dissenting) (concluding that §102(b) should have applied to a paper where "its distribution to American and

Canadian gas companies establishes that by 1994, far from attempting to keep details about its device secret, Meter was actively publishing them."); *SRI Int'l, Inc. v. Internet Sec. Sys., Inc.*, 511 F.3d 1186, 1201-05 (Fed. Cir. 2008) (Moore, J., dissenting in part) (attempting to harmonize prior cases); *Bruckelmyer*, 453 F.3d at 1355 (Newman, J., dissenting) ("We should maintain a consistent and reliable standard of what constitutes a 'printed publication.'"). The frequency of such dissents favors Supreme Court review of this issue, which has the potential to affect almost every patent case where the inventor practices or exploits the invention prior to filing for a patent.

### D. District court caselaw further highlights the inconsistent construction of "printed publication" in patent cases.

Recent decisions from district courts have further highlighted the uncertainty regarding the application of the Federal Circuit's precedent. Some district courts have continued to apply the original bright-line rule that dissemination without confidentiality obligations constitutes "publication." *See, e.g., Transocean Offshore Deepwater Drilling, Inc. v. GlobalSantaFe Corp.*, 443 F. Supp. 2d 836, 848 (S.D. Tex. 2006) (finding that testimony about the brochure's "distribut[ion] without restriction . . . is sufficient to raise a genuine issue of material fact concerning whether the brochure was 'published'"); *OKI Am., Inc. v. Advanced Micro Devices, Inc.*, No. C04-03171 CRB, 2006 WL 2711555, *5 (N.D. Cal. Sept. 21, 2006) ("[I]f the recipients are allowed to share the contents of a report with others,

the report is considered 'accessible,' and therefore a printed publication.") (citing *Cooper Cameron*, 291 F.3d at 1323-24).

But other district courts have applied the Federal Circuit's new case-by-case analysis without regard for the original bright-line rule. *See Lucent Techs., Inc. v. Gateway, Inc.*, No. 02-cv-2060-B, 2007 WL 1877983 (S.D. Cal. June 27, 2007) ("The determination of accessibility is not rooted in strict rules."); *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, No. 95-218-SLR, 1998 WL 151411, *37 (D. Del. Mar. 13, 1998) (holding that "limited distribution, even to those of skill in the art, does not amount to public accessibility"), *aff'd*, 228 F.3d 1338 (Fed. Cir. 2000).

And some district courts have further illustrated this uncertainty by requiring both "publication" and also "public accessibility." *SPX Corp. v. Bartec USA, LLC*, No. 06-cv-14888, 2008 WL 1701641 at *8 (E.D. Mich. Apr. 10, 2008) (requiring that the reference be both locatable by the interested public and also "actually disseminated"); *Bradford Co. v. Afco Mfg.*, No. 1:05-cv-449, 2008 WL 570963, *4 (S.D. Ohio Feb. 28, 2008) (finding that the Federal Circuit's precedent imposed "other requirements for 'public accessibility'" beyond being "published and disseminated"). This confusion among district courts further supports Supreme Court review of the correct standard to apply.

## III. The Federal Circuit's decision in this case is internally inconsistent and fails to apply controlling precedent.

As set forth above, the *Garrett Corp.* and *MIT* line of cases hold that dissemination of a printed

document to commercial companies and individuals—without confidentiality obligations—constitutes "publication" under 35 U.S.C. § 102(b). The Monograph was disseminated without confidentiality obligations to at least two commercial companies, two university committees and eight individuals of skill and interest in the art prior to the critical date for the Palmaz '762 patent. The Monograph contained no confidentiality notice, and there is no evidence from any of the recipients regarding any purported confidentiality obligation. Notably, Dr. Palmaz's contracts with the commercial recipients empowered those recipients to further disseminate or exploit the Monograph however they saw fit. The Monograph is a "printed publication" under the 1836 application of the phrase, under a modern plain-language construction, and in light of the policy basis for the "loss of right to patent" provision.

In ruling that the Monograph was not a "printed publication," the Federal Circuit relied on: (1) Dr. Palmaz's purported subjective expectation of confidentiality; and (2) alleged incentives for inventors and commercial companies exploiting inventions. Even if the Court were not to review the correct standard to apply for all "printed publications," the Federal Circuit's errors on these two issues warrant reversal in this case.

### A. The Federal Circuit improperly relied on Dr. Palmaz's uncorroborated litigation testimony regarding his purported subjective intent.

As the Federal Circuit found, no legal confidentiality obligations bound the commercial recipients of the Monograph. App. 26a-27a. But in holding that Dr. Palmaz's dissemination of his Monograph to these commercial companies was not a "printed publication," the Federal Circuit credited Dr. Palmaz's decades-later, uncorroborated litigation testimony—that he thought this dissemination was somehow confidential—over the written instruments that defined his relationships with the commercial companies. App. 30a.

This was improper as a matter of law. *See Stevenson v. Oceanic Bank*, 223 Cal. App. 3d 306, 316 (Cal. Ct. App. 1990) ("[T]he rules of interpretation of written contracts are for the purpose of ascertaining the meaning of the *words used* therein; evidence cannot be admitted to show intention independent of the instrument.") (emphasis in original). Moreover, it should not even have been considered given the procedural posture of the case, *i.e.*, on summary judgment against Boston Scientific. *Hill v. Scranton*, 411 F.3d 118, 132 n. 22 (3d Cir. 2005) ("[W]hen evaluating a summary judgment motion a court should not consider . . . testimony of an interested witness where that testimony supports the movant."). And by crediting Dr. Palmaz's testimony over the contrary record evidence, the appellate panel failed to "resolve all factual doubts and draw all reasonable inferences in favor of [] the nonmoving

party." *DL Res., Inc. v. FirstEnergy Solutions Corp.*, 506 F.3d 209, 216 (3d Cir. 2007). In any event, inventor testimony regarding invalidity issues often requires corroboration. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1065 (Fed. Cir. 2005) ("[B]ecause of the danger in post-hoc rationales by an inventor ... the court requires objective evidence to corroborate an inventor's testimony . . ."). No corroboration exists for Dr. Palmaz's testimony.

As the Federal Circuit's opinion depended on an alleged confidential relationship, the court erred in relying on interested, uncorroborated testimony that was contradicted by controlling legal instruments. If this were the correct standard, every inventor could salvage an invalid patent by merely testifying that they expected their prior exploitation of their inventions to remain confidential. Such an approach flaunts the rules of evidence and eviscerates the bright-line limitations of § 102(b).

### B. The Federal Circuit erred in evaluating purported incentives for inventors and the Monograph recipients.

Additionally, the Federal Circuit erred in substituting its own policy judgment regarding "public accessibility" for the mandated statutory analysis of "printed" and "publication." Throughout its opinion, the Federal Circuit tellingly resorts to discussions of "the importance of '*preser[ving] the incentive* for inventors to participate in academic presentations and discussions'" and whether "these or similar commercial entities *had an incentive* to make the document available, etc." App. 29a, 31a (emphasis added). Such an analysis of, and reliance

on, the Federal Circuit's policy concerns belies any purported application of Congress' bright-line rule.

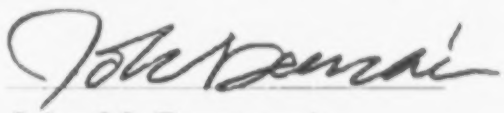
The appellate panel's discussion of the "limited number of entities" who received the Monograph and inquiry into whether the commercial recipients would have republished the Monograph confirms the court's policy-based analysis of whether—in the Federal Circuit's view—an invention was sufficiently public to invalidate a patent. This is an inappropriate legislative role for the court to assume. Notably, no precedent of this Court condones consideration of such "incentives" as factors in evaluating whether a document should be deemed a "printed publication" under § 102(b). Rather, controlling precedent has held that a single act triggers § 102(b)—a single sale, a single use and also a single publication. The bright-line promulgated by Congress was crossed in this case, and the Federal Circuit's failure to recognize that breach and deem the Monograph an invalidating "printed publication" warrants reversal.

## CONCLUSION

For all of the foregoing reasons, this Court should grant the petition for writ of certiorari.

September 24, 2009

Respectfully submitted,



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# APPENDIX

# APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED MARCH 31, 2009

## UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2008-1003, -1072

CORDIS CORPORATION,

Plaintiff-Appellant,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in case no. 03-CV-027, Judge Sue L. Robinson.

DECIDED: March 31, 2009

Before MAYER and DYK, Circuit Judges, and HUFF, District Judge.*

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* Honorable Marilyn L. Huff, District Judge, United States District Court for the Southern District of California, sitting by designation.

*Appendix A*

DYK, *Circuit Judge.*

Cordis Corporation ("Cordis") appeals, and Boston Scientific Corporation and Scimed Life Systems, Inc. ("Boston Scientific") cross-appeal, from a final judgment of the United States District Court for the District of Delaware. The judgment was based on two separate jury verdicts of infringement: (1) infringement by Boston Scientific of claims 1 and 23 of U.S. Patent No. 4,739,762 ("the '762 patent") and claim 2 of U.S. Patent No. 5,895,406 ("the '406 patent"), and (2) infringement by Cordis of claim 36 of U.S. Patent No. 5,922,021 ("the '021 patent"). The judgment also determined that those claims were not invalid. *Cordis Corp. v. Boston Scientific Corp.*, Civ. No. 03-027-SLR, 2007 WL 2775087 (D.Del. Sept. 24, 2007) (judgment). With one minor exception, we affirm.

## BACKGROUND

Cordis and Boston Scientific own patents relating to intravascular stents, which are cylindrical lattice-like scaffolds inserted into a blood vessel and then expanded, often by using a balloon catheter, in order to hold the vessel open. Cordis owns the '762 patent and the '406 patent, and Boston Scientific owns the '021 patent.

In January 2003, Cordis filed suit against Boston Scientific, alleging that several of Boston Scientific's stents infringe various claims of the '762 patent and the '406 patent. Boston Scientific counterclaimed, alleging that several of Cordis's stents infringe various claims of

the '021 patent. The district court denied Cordis's motion for a preliminary injunction against sales of one of Boston Scientific's stents, and we affirmed. *Cordis Corp. v. Boston Scientific Corp.*, 99 Fed.Appx. 928 (Fed.Cir.2004).

We treat the Cordis claims and the Boston Scientific claims separately. Since Cordis is the appellant, we first discuss Boston Scientific's claims against Cordis that are the subject of the Cordis appeal.

*The Boston Scientific claims:* The jury returned a verdict in July 2005 that (a) Cordis's Cypher, BX Velocity, BX Sonic, and Genesis stents do not literally infringe claim 36 of the '021 patent; (b) "the Cypher, BX Velocity, BX Sonic and Genesis stents infringe the 'corners' limitation of claim 36 of the '021 patent under the doctrine of equivalents"; and (c) claim 36 of the '021 patent is not invalid for obviousness. *Cordis Corp. v. Boston Scientific Corp.*, Civ. No. 03-027-SLR, 2006 WL 1305227, at *1 (D.Del. May 11, 2006) ("*Memorandum Opinion*"). The district court denied Cordis's motion for judgment as a matter of law or, in the alternative, a new trial.

*The Cordis claims:* On summary judgment, the district court determined that claims 1 and 23 of the '762 patent were not invalid. A separate jury returned a verdict in favor of Cordis in June 2005 that (a) Boston Scientific's Express, Taxus Express, Express Biliary, and Libert é stents literally infringe claim 23 of the '762 patent; (b) Boston Scientific induced literal infringement

of claim 1 of the '762 patent with respect to these stents; (c) the Libert é stent literally infringes claim 2 of the '406 patent; and (d) claim 2 of the '406 patent is neither anticipated nor rendered obvious by the prior art. The district court denied Boston Scientific's motion for judgment as a matter of law or, in the alternative, a new trial.

After the district court entered judgment, Cordis and Boston Scientific both timely appealed. We have jurisdiction under 28 U.S.C. §§ 1291, 1292(c)(2), and 1295(a)(1).

## DISCUSSION

We review the denial of a motion for judgment as a matter of law without deference, and we review the denial of a motion for a new trial for abuse of discretion. *Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1318 (Fed. Cir. 2003). Each party raises issues that have little merit. We dispose of those arguments summarily, reserving more extended discussion for the few issues that merit attention.

### I

We first address Cordis's appeal.

#### A. *"Wherein" clause construction*

Cordis challenges the judgment that its BX Velocity stent infringes claim 36 of the '021 patent. Claim 36

depends from claim 24, which in turn depends from claim 23. '021 patent col.22 l.42, col.21 l.16.

The procedural posture of this issue is unclear. The jury found that the accused Cordis stents do not literally infringe claim 36 of the '021 patent. Instead of addressing whether Cordis's stents infringed claim 36 under the doctrine of equivalents, the jury was asked only to determine whether Cordis's stents "infringe the 'corners' limitation of claim 36 of the '021 patent under the doctrine of equivalents." J.A. at 11,238. The jury found that the "corners" limitation was infringed under the doctrine of equivalents. Apparently the parties agreed that the BX Velocity stent infringes all limitations of claim 36 (if properly construed by the district court) except the "corners" limitation, but the parties provided no reference in the record reflecting this agreement. However, the district court entered judgment of infringement of claim 36, and we assume that the judgment rests upon such an agreement.

Cordis first argues that the district court erred in construing the "wherein" clause of claim 23, and that under a proper construction of this clause Cordis's BX Velocity stent does not infringe claim 36.[1] The "wherein" clause of claim 23 describes how the struts within one expansion column or ring of a stent are connected to the struts of another column or ring,

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1. This argument does not apply to Cordis's Cypher, BX Sonic, and Genesis stents.

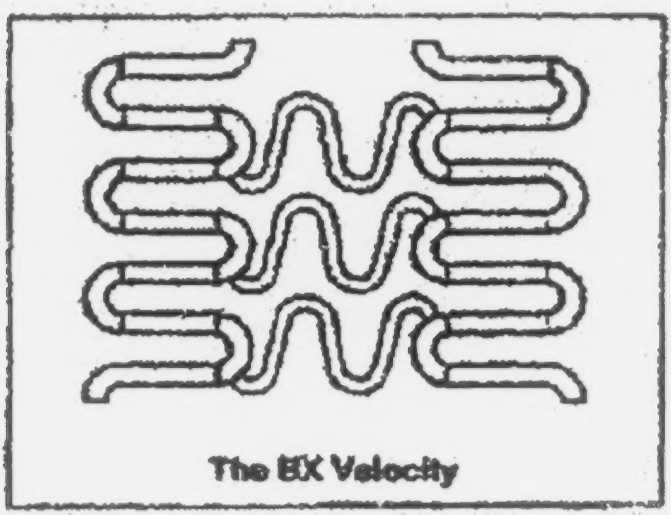
> *wherein* the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

'021 patent col.21 ll.11-15 (emphasis added). The district court construed this "wherein" clause in claim 23 to mean "the first expansion strut in the first column does not share a longitudinal axis with the second expansion strut in the second column." *Cordis Corp. v. Boston Scientific Corp.*, Civ. No. 03-027-SLR, 2005 WL 1322966, at *2 (D.Del. June 3, 2005) ("*Claim Construction*"). The district court refused to construe the "wherein" clause in claim 23 to exclude so-called "180 degrees out of phase" stent designs.

Claim construction is an issue of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996), that we review without deference, *Cybor Corp. v. FAS Technologies Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

Cordis urges that the district court's construction improperly failed to exclude stents whose strut pairs are arranged "180 degrees out of phase," a phrase that both parties agree is in common usage in stent design. In such a 180-degree out-of-phase arrangement, the struts within each expansion column or ring are connected to form pairs, and the connected ends of the

pairs in one ring face the connected ends of the pairs in the next ring, forming a mirror-image pattern. Cordis argues that if claim 23 excludes such 180-degree out-of-phase designs, then Cordis's BX Velocity stent (which uses a 180-degree out-of-phase design) would not infringe claim 36. Cordis illustrated the 180-degree out-of-phase design with a diagram:




Br. for Pl.-Appellant Cordis Corp. 3.

Cordis argues that the same "wherein" clause appears in both claim 1 and claim 23; that the clauses must have the same meaning; and that the prosecution history shows that the "wherein" clause excludes 180-degree out-of-phase designs. Cordis's argument is a bit confusing. The issue is not the meaning of the "wherein"

clause. Rather, the problem stems from the fact that claim 23 and claim 1 use different numbering systems, so that, for example, the "first expansion strut of the second expansion strut pair in the second expansion column" is not the same strut in claim 23 as in claim 1.

Under the numbering system of claim 1, each strut in a column or ring is either the "first" or "second" strut of a pair, each pair in the first ring is a "first . . . pair," and each pair in the second ring is a "second . . . pair."[2]

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2. Claim 1 of the '021 patent states:

1. A stent in a non-expanded state, comprising:

a *first expansion strut pair* including a *first expansion strut* positioned adjacent to a *second expansion strut* and a joining strut of the first expansion strut pair that couples the first and second expansion struts at a distal end of the first expansion strut pair, a *plurality of the first expansion strut pair forming a first expansion column;*

a *second expansion strut pair* including a *first expansion strut* positioned adjacent to a *second expansion strut* and a joining strut of the second expansion strut pair that couples the first and second expansion struts of the second expansion strut pair at a proximal end of the second expansion strut pair, a *plurality of the second expansion strut pair forming a second expansion column;*

(Cont'd)

*Appendix A*

Thus in claim 1, the "wherein" clause requires the first strut of every strut pair in the first ring to be offset from the first strut of every strut pair in the second ring, which would not be possible in a 180-degree out-of-phase design. However, under the numbering system of claim 23, each strut in a ring is individually numbered

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(Cont'd)

> a first connecting strut including a first connecting strut proximal section, a first connecting strut distal section and a first connecting strut intermediate section, the first connecting strut proximal section being coupled to the distal end of the first expansion strut pair in the first expansion column and the first connecting strut distal section being coupled to the proximal end of the second expansion strut pair of the second expansion column, a plurality of the first connecting strut forming a first connecting strut column that couples the first expansion column to the second expansion column, the first connecting strut intermediate section being non-parallel to the first connecting strut proximal and distal sections, *wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.*

'021 patent col. 18 ll.9-41 (emphases added).

*Appendix A*

"first . . . second . . . third . . . fourth . . . ," each pair in the first ring is individually numbered "first . . . second . . . third . . . fourth . . . ," and each pair in the second ring is individually numbered "first . . . second . . . third . . . fourth . . . ."[3] Thus in claim 23, the "wherein" clause

3. Claim 23 of the '021 patent states:

23. A stent in a non-expanded state, comprising:

a first expansion column formed of a plurality of first expansion column strut pairs, a *first expansion strut pair* including a first *expansion strut* adjacent to a *second expansion strut* and a first joining strut that couples the first and second expansion struts at a proximal end of the first expansion strut pair, *a second expansion strut pair* including a *third expansion strut* adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a *third expansion strut pair* including a *fourth expansion strut* adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a *fourth expansion strut pair* including a *fifth expansion strut* adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the

(Cont'd)

*Appendix A*

(Cont'd)

fourth expansion strut pair, a first expansion strut pair *first corner* formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair *second corner* formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair *first corner* formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair *second corner* formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair *first corner* formed where the third joining strut is coupled to the third expansion strut, and a third expansion strut pair *second* corner formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first corner formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair *second* corner formed where the fourth joining strut is coupled to the fifth expansion strut;

a second expansion column formed of a plurality of second expansion column strut pairs, a *first expansion strut pair* including a *first expansion strut* adjacent to a *second expansion* strut and a first joining strut that couples the first and second expansion struts at a proximal

(Cont'd)

*Appendix A*

(Cont'd)

end of the first expansion strut pair, a *second expansion strut pair* including a *third expansion* strut adjacent to the second expansion strut and a second joining strut that couples the second and third expansion struts at a distal end of the second expansion strut pair, a third *expansion strut pair* including a *fourth expansion strut* adjacent to the third expansion strut and a third joining strut that couples the third and fourth expansion struts at a proximal end of the third expansion strut pair, a *fourth expansion strut pair* including a *fifth expansion strut* adjacent to the fourth expansion strut and a fourth joining strut that couples the fourth and fifth expansion struts at a distal end of the fourth expansion strut pair, a first expansion strut pair *first corner* formed where the first joining strut is coupled to the first expansion strut, and a first expansion strut pair *second corner* formed where the first joining strut is coupled to the second expansion strut, and a second expansion strut pair *first corner* formed where the second joining strut is coupled to the second expansion strut, and a second expansion strut pair *second corner* formed where the second joining strut is coupled to the third expansion strut, and a third expansion strut pair *first corner* formed where the third joining strut is coupled to the third

(Cont'd)

*Appendix A*

(Cont'd)

expansion strut, and a third expansion strut pair *second corner* formed where the third joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair first *corner* formed where the fourth joining strut is coupled to the fourth expansion strut, and a fourth expansion strut pair *second corner* formed where the fourth joining strut is coupled to the fifth expansion strut; and

a first connecting strut column formed of a plurality of first connecting struts, each connecting strut of the first connecting strut column including a connecting strut proximal section, a connecting strut distal section and a connecting strut intermediate section, a first connecting strut proximal section is coupled to the joining strut of the second expansion strut pair of the first expansion strut column, and a first connecting strut distal section is coupled to the joining strut of the first expansion strut pair of the second expansion strut column, and a second connecting strut proximal section is coupled to the joining strut of the fourth expansion strut pair of the first expansion strut column, and a second connecting strut distal section is coupled to the joining strut of the third expansion strut pair of the second expansion strut column, the first connecting strut

(Cont'd)

requires only one specific strut (the first strut of the first pair in the first ring) to be offset from one other specific strut (the "first expansion strut of the second expansion strut pair" in the second ring). Cordis numbered a figure from the '021 patent (also known as

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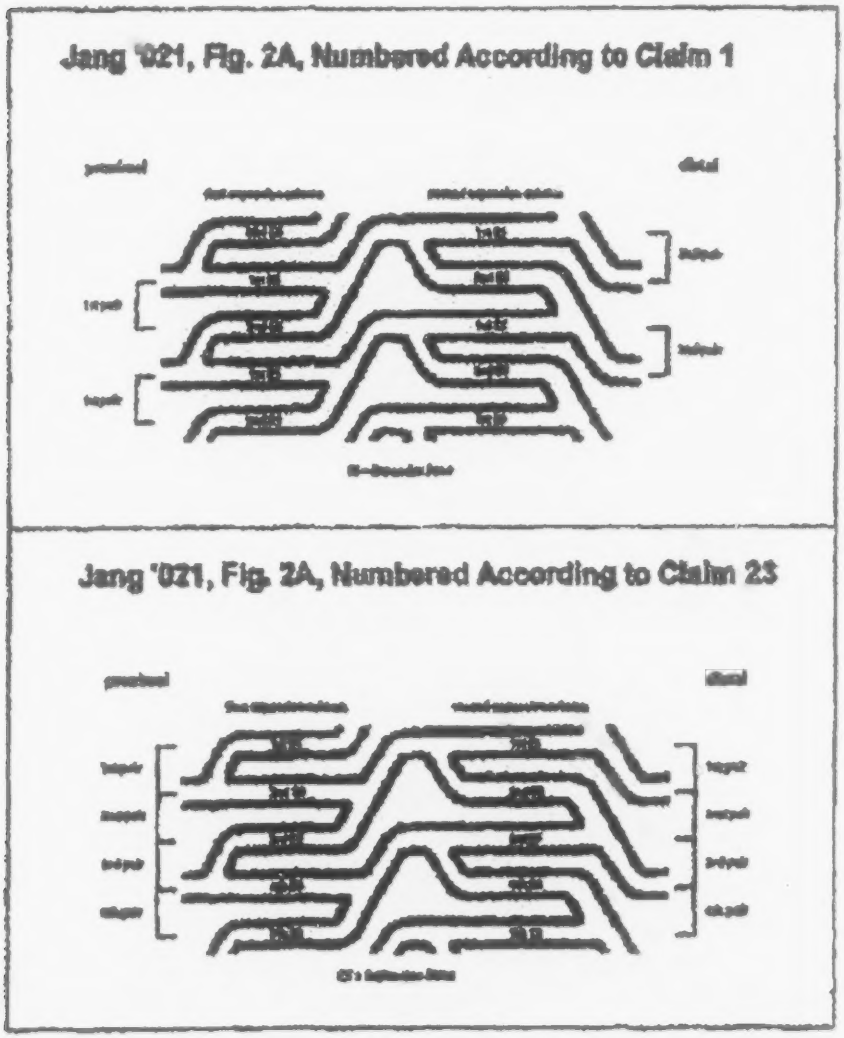
(Cont'd)

> intermediate section being non-parallel to the first connecting strut proximal and distal sections *wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.*

'021 patent col. 19 l.53-col.21 l.15 (emphases added).

the Jang patent) to illustrate these different numbering systems:




Br. for Pl.-Appellant Cordis Corp. 40. Because these two specific struts could be offset from each other but yet aligned with other struts to form a 180-degree out-of-

phase pattern, the language of claim 23 includes 180-degree out-of-phase designs. Indeed, the parties appear to agree that on their face claim 1 and claim 23 each use a different numbering system to describe the relative arrangement of a stent's struts, with the result that the claim 23 "wherein" clause does not exclude 180-degree out-of-phase designs. The question is whether the prosecution history requires that, despite its plain language, the "wherein" clause of claim 23 be construed to use the same numbering system as claim 1. Cordis argues that the prosecution history reflects such a "clear and unmistakable" disclaimer. *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1353 (Fed.Cir.2005); *see also Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed.Cir.2003). We cannot agree.

The "wherein" clause was added to claims 1 and 23 during the prosecution of the '021 patent after the examiner rejected both claims as anticipated by European Patent Application No. 95307687.4, Pub. No. 0 709 067 A2 ("Pinchasik"). Pinchasik discloses a stent whose struts are arranged in a 180-degree out-of-phase design but whose struts are not numbered. During the first office action, the examiner rejected claims 1 and 23 as anticipated by Pinchasik, coloring one of Pinchasik's stent design figures and numbering parts of the figure (labeled "Figure 2") according to the numbering system of claim 1 of the '021 patent.[4] The examiner's numbering

4. The exhibit included at page 7994 of the Joint Appendix shows that the examiner colored in and labeled the figure from Pinchasik, but does not disclose numbering of the figure by the (Cont'd)

system is, however, different than claim 23's numbering system. The examiner's rejection in light of Pinchasik made no reference to 180-degree out-of-phase designs, but simply stated that claim 1, claim 23, and other claims "are rejected under 35 U.S.C. § 102(b) as being anticipated by Pinchasik" and that "[w]ith respect to [these claims] . . . refer to the modified Figure 2 attached to this office action." J.A. at 1705. After the "wherein" clause was added to claims 1 and 23, the examiner allowed both claims. Cordis argues that the examiner used only the numbering system of claim 1 when allowing both claim 1 and claim 23, and that the examiner necessarily assumed that claim 23 used the same numbering system as claim 1. However, the examiner did not say so, and we cannot simply suppose that the claims were allowed based on an assumed identity of numbering systems. We note that Cordis does not argue that Pinchasik anticipates claim 23 of the '021 patent under the district court's claim construction, which suggests that the examiner could have allowed the claim on other grounds. Cordis also argues that both the applicant and the examiner referred to stent pairs as "longitudinally offset," but these references simply repeat the "wherein" clause and say nothing about different numbering systems. Finally, on the disclaimer issue, Cordis argues that the '021 patent's provisional application described the invention as consisting of

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(Cont'd)

examiner. The parties appear not to dispute that the examiner did number the figure according to the numbering system of claim 1 of the '021 patent.

stents whose flexibility depended on connections between "split level" (and thus offset) strut pairs, but again this language in the provisional application did not discuss the system for numbering these connected strut pairs. A disclaimer must be "clear and unmistakable," and unclear prosecution history cannot be used to limit claims. *Free Motion Fitness*, 423 F.3d at 1352-53; *see also Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1381-82 (Fed. Cir. 2002). The plain language of claim 23 cannot be overcome by such unclear prosecution history. Although Cordis urges that no figure in the ' 021 patent uses a 180-degree out-of-phase design, a patent is not confined to its disclosed embodiments. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc).

We affirm the district court's construction of the "wherein" clause in claim 23 of the '021 patent.

B. *Corners limitation*

Alternatively, Cordis argues that the judgment of infringement of claim 36 of the '021 patent by the BX Velocity stent should be set aside, because the jury erred in concluding that the "corners" limitation of claim 36 was satisfied under the doctrine of equivalents, and because the district court erred in denying judgment as a matter of law on this ground. The "corners" limitation appears both in the language of claim 36 itself

and in claim 23, on which claim 36 depends.[5] Cordis does not dispute the district court's construction of "corners" as "a place where two surfaces meet to form an angle." *Claim Construction,* 2005 WL 1322966, at *1.

First, Cordis argues that the evidence did not support the jury's verdict of infringement of this limitation under the doctrine of equivalents. A jury's determination of infringement is a question of fact that we review to consider whether it is supported by substantial evidence. *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1423 (Fed.Cir.1997).

The district court properly found that Boston Scientific presented sufficient expert testimony that Cordis's BX Velocity stent meets the "corners" limitation

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5. Claim 36 of the '021 patent states:

> 36. The stent of claim 24, wherein the first connecting strut proximal section is coupled to the *second corner* of the second expansion strut pair of the first expansion strut column, and the first connecting strut distal section is coupled to the *first corner* of the first expansion strut pair of the second expansion strut column, and the second connecting strut proximal section is coupled to the *second corner* of the fourth expansion strut pair of the first expansion strut column, and the second connecting strut distal section is coupled to the *first corner* of the third expansion strut pair of the second expansion strut column.

'021 patent col.22 ll.42-52 (emphases added).

of claim 36 under the doctrine of equivalents under the function-way-result test of *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950), a test that is still useful under *Warner-Jenkinson Co. v. Hilton-Davis Chemical Co.*, 520 U.S. 17, 39-40 (1997), particularly for mechanical inventions. Boston Scientific's expert Dr. Moore testified that the "corners" in claim 36 and the circular arcs or rounded corners of the BX Velocity stent both function as actual and potential reference points for joining adjacent stent rings, fulfill this function through their similar locations, and can or do result in offset connections between stent rings. Such testimony fulfills Boston Scientific's obligation to "provide particularized testimony and linking argument . . . with respect to the function, way, result test when such evidence is presented to support a finding of infringement under the doctrine of equivalents." *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996).

Cordis next argues that the doctrine of equivalents should not be applied in this case because the jury's finding of infringement vitiated the "corners" limitation.[6] Cordis asserts that the circular arcs of the BX Velocity stent cannot "form an angle" as required by the district court's claim construction. Whether the doctrine of equivalents vitiated a patent claim is a question of law we review de novo. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d 1364, 1379 (Fed. Cir. 2005).

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6. Cordis also argues that circular arcs were disclaimed. We find no basis for this in the prosecution history of the '021 patent.

The district court properly found that vitiation did not bar a doctrine of equivalents analysis here. Although we have "refused to apply the doctrine [of equivalents] . . . where the accused device contained the antithesis of the claimed structure," Planet *Bingo, LLC v. GameTech International, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2006), the circular arcs of the BX Velocity are not antithetical to the "corners" limitation in claim 36 of the '021 patent. Boston Scientific's theory that the circular arcs of the BX Velocity stent are equivalent to the "corners" in claim 36 does not vitiate the "corners" limitation, because it does not "render[ ] the pertinent limitation meaningless," *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1359 (Fed. Cir. 2005), or "effectively eliminate that element in its entirety," *Warner-Jenkinson*, 520 U.S. at 29. *See Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 850 (Fed. Cir. 2006).

We affirm the district court's denial of Cordis's motions for judgment as a matter of law or, in the alternative, a new trial on infringement of the '021 patent.

### C. *New claim construction arguments*

Cordis argues that the district court improperly declined after trial to adopt a new construction of "expansion columns" and "connecting strut columns" in the claims of the '021 patent. In a motion for judgment as a matter of law on infringement of the '021 patent, Cordis raised for the first time the argument that the

district court should adopt the construction of these terms that Boston Scientific had advocated in a different case relating to the '021 patent.[7] The district court declined to do so. *Cordis Corp. v. Boston Scientific Corp.*, Civ. Nos. 03-027-SLR, 03-283-SLR, 2007 WL 2775087, at *1 (D.Del. Sept. 24, 2007).

Raising this argument for the first time in a motion for judgment as a matter of law more than a year after the jury's infringement verdict was too late. "[L]itigants waive their right to present new claim construction disputes if they are raised for the first time after trial." *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006); *see also Abbott Labs. v. Syntron Bioresearch, Inc.* 334 F.3d 1343, 1357 (Fed. Cir. 2003). The district court properly declined to revise its claim construction in response to Cordis's argument.

D. *Indefiniteness*

Cordis asserts that the district court erred in finding that claim 23 of the '021 patent is not indefinite. Cordis argues that claim 36, and claim 23 on which it depends, are invalid unless claim 23's "wherein" clause is construed to exclude 180-degree out-of-phase designs. Indefiniteness under 35 U.S.C. § 112 ¶ 2 is an issue of claim construction and a question of law that we review

7. The claim construction Cordis urged the district court to adopt was appealed to this court and has since been vacated and remanded. *Jang v. Boston Scientific Corp.*, 532 F.3d 1330, 1331 (Fed. Cir. 2008).

de novo. *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008). We see no basis for Cordis's argument. Claim 23 as construed by the district court is not indefinite.

### E. *Obviousness*

Cordis argues that the jury erred in finding that claim 36 of the '021 patent was not invalid for obviousness, and that the district court erred in denying Cordis's motion for judgment as a matter of law of obviousness.

The '021 patent claims priority to its provisional application. '021 patent col.1 ll.6-8. Cordis first argues that the district court should have ruled as a matter of law that the '021 patent was not entitled to a priority date of April 26, 1996 (when the '021 patent's provisional application was filed), and that the correct priority date is April 25, 1997 (when the '021 patent's non-provisional application was filed). Cordis asserts that the priority date is important because after April 26, 1996, and before April 25, 1997, inventors had created stents that demonstrated that claim 36 of the '021 patent was invalid as obvious under 35 U.S.C. § 103. Cordis's basis for challenging the priority date is its theory that the '021 patent's April 1996 provisional application did not provide a sufficient written description of the patent's limitations, namely the limitation of claim 36 requiring connecting struts to be attached on one end at a "second" or bottom corner of a strut pair and on the other end at a "first" or top corner.

*Appendix A*

The written description requirement of 35 U.S.C. § 112 ¶ 1 is a question of fact, and we review a jury's findings of fact relating to the written description requirement for substantial evidence. *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1243 (Fed. Cir. 2002). To comply with the written description requirement, an applicant must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention," *New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1295 (Fed. Cir. 2002) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991) (emphasis omitted)), namely that he or she "had invented each feature that is included as a claim limitation," *New Railhead*, 298 F.3d at 1295. The district court cited uncontradicted testimony from Boston Scientific's expert Dr. Moore that the '021 patent's provisional application provided a sufficient written description of the limitations of claim 36. We conclude that the jury could properly find that the '021 patent was entitled to an April 1996 priority date.

Cordis alternatively argues that regardless of whether the '021 patent has a priority date of April 1996 or April 1997, several earlier patents[8] were prior art rendering claim 36 obvious. Cordis asserts that it would have been obvious to one of ordinary skill in the art to combine features of these patents to create stents with the bottom-corner-to-top-corner connecting struts disclosed in claim 36 of the '021 patent.

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8. U.S. Patent Nos. 5,102,417; 5,449,373; 5,643,312; 5,733,303; and 6,348,065.

"We review '[the] jury's conclusions on obviousness, a question of law, without deference, and the underlying findings of fact . . . for substantial evidence.' " *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1345 (Fed.Cir.2008) (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)). The district court cited uncontradicted testimony from Boston Scientific's expert Dr. Moore that the prior art patents cited by Cordis would be unlikely to be combined to create the connectors of claim 36 of the '021 patent, and that these prior art patents taught away from the bottom-to-top connectors described in claim 36 by describing features of such connectors as potentially harmful. The district court properly concluded there was substantial evidence that these prior art patents did not render claim 36 obvious.

We affirm the district court's denial of Cordis's motion for judgment as a matter of law or, in the alternative, a new trial on invalidity of the '021 patent.

II

We next address Boston Scientific's cross-appeal.

A. *Monographs*

Boston Scientific argues that the district court erred in holding that two monographs prepared by the inventor of the '762 patent are not prior art, and erred in granting Cordis's motion for summary judgment that the asserted claims of the '762 patent are not invalid "as to the asserted claims being invalidated by the

Palmaz Monographs." *Cordis Corp. v. Boston Scientific Corp.*, Civ. No. 03-027-SLR (D. Del. June 3, 2005) (summary judgment order).

If there are no facts in dispute, whether a reference is a prior art "printed publication" within the meaning of 35 U.S.C. § 102(b) is a question of law.[9] *In re Klopfenstein*, 380 F.3d 1345, 1347 (Fed. Cir. 2004). Because the facts of the distribution of Dr. Palmaz's monographs are not in dispute, we review de novo the issue of whether the monographs are prior art printed publications.

In 1980 the inventor of the '762 patent, Dr. Palmaz, prepared a ten-page paper describing his work on stents. This paper is the "1980 monograph." At that time he was a resident at a hospital in California. His name was not on the paper. He gave copies of the paper to approximately six of his teachers at an oral presentation of his work to these physicians and several other colleagues. Pursuant to agreements, Palmaz later gave copies of the monograph to two companies (Vascor, Inc., and Shiley, Inc.) while attempting to commercialize his stent technology.[10] Neither agreement required

9. Under 35 U.S.C. § 102, "[a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."

10. The parties here agree that there is no evidence that copies of the monographs were given to a third commercial entity, Cook Inc., before the critical date of the '021 patent.

confidentiality, and the Shiley agreement specifically stated that Shiley "shall not be committed to keep secret any idea or material submitted." J.A. at 19,473. In 1983 Dr. Palmaz revised the paper; the revised paper became the "1983 monograph." In 1983 he also gave a copy of both monographs to Werner Schultz, a technician from whom Dr. Palmaz was seeking fabrication assistance. When Dr. Palmaz joined the faculty in 1983 at the University of Texas, San Antonio, he gave a copy of the 1983 monograph to a doctor there (who then gave it to the technician setting up Dr. Palmaz's laboratory) and to the university as part of a research proposal. Dr. Palmaz applied for the patent that became the '762 patent in 1985.

A document is publicly accessible if it "has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it and recognize and comprehend therefrom the essentials of the claimed invention without need of further research or experimentation." *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981) (quoting *I.C.E. Corp. v. Armco Steel Corp.*, 250 F. Supp. 738, 743 (S.D.N.Y. 1966)). In general, "[a]ccessibility goes to the issue of whether interested members of the relevant public could obtain the information if they wanted to." *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988). Many of our cases in this area have concerned publications available in libraries, and the question has been whether the publication has been sufficiently indexed to be publicly accessible. *See, e.g., In re Cronyn*,

890 F.2d 1158, 1161 (Fed. Cir. 1989); *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986); *In re Wyer*, 655 F.2d at 226. Other cases have involved widespread distribution so that the public could easily obtain copies of the publication. *See, e.g., Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350-51 (Fed. Cir. 2008).

Here we have a somewhat different question: whether the distribution to a limited number of entities without a legal obligation of confidentiality renders the monographs printed publications under § 102(b). We have held that where a distribution is made to a limited number of entities, a binding agreement of confidentiality may defeat a finding of public accessibility. But we have also held that such a binding legal obligation is not essential. *Klopfenstein*, 380 F.3d at 1351. We have noted that "[w]here professional and behavioral norms entitle a party to a reasonable expectation" that information will not be copied or further distributed, "we are more reluctant to find something a 'printed publication.' "[11] *Id.* at 1350-51.

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11. In the public use context of § 102(b), we have similarly noted that a lack of an express promise of confidentiality is not determinative of public use, but is instead "one factor to be considered in assessing all the evidence." *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371, 1379 (Fed. Cir. 2004) (quoting *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986)), *abrogated on other grounds by Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed.Cir.2008) (en banc); *see also Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1382 (Fed. Cir. 2005).

*Appendix A*

We first discuss Dr. Palmaz's distribution of copies of his monographs to his university and hospital colleagues. We have recognized the importance of "preserv[ing] the incentive for inventors to participate in academic presentations or discussions" by noting that professional norms may support expectations of confidentiality. *Id.* at 1351. The record here contains clear evidence that such academic norms gave rise to an expectation that disclosures will remain confidential.[12] Cordis's expert Dr. Buller testified that the "code of practice which occurs worldwide in academic circles, in departments, in medicine" includes treating a document describing scientific research in the "same confidential manner as you would if you had been given it directly by the author." J.A. at 8540-41. The district court properly concluded that Dr. Palmaz's distribution of the monographs to his academic and research colleagues did not render the monographs prior art printed publications.

However, Boston Scientific urges that, even if the academic and hospital distributions did not create public accessibility, the distribution of monographs to two commercial entities did so. These distributions occurred during attempts to interest the two companies in

12. The only potentially contrary testimony is a statement in a report by Boston Scientific's expert that a "colleague, faculty member or other recipient [of the monographs] . . . would be under no obligation to maintain the disclosure in confidence." J.A. at 19,386. As we have discussed, whether or not recipients have a legal obligation to maintain confidentiality is not determinative.

development of Dr. Palmaz's stent designs. There is no claim here that the two commercial entities provided any express agreement to keep the document confidential; indeed, one entity's disclosure agreement did not discuss the entity's confidentiality obligations, and the other entity's disclosure agreement specifically disclaimed such obligations (most likely to avoid a lawsuit resulting from inadvertent disclosure). Boston Scientific argues that under the decision of our predecessor court, the Court of Claims, in *Garrett Corp. v. United States*, "[w]hile distribution [of a government report] to government agencies and personnel alone may not constitute publication, distribution to commercial companies without restriction on use clearly does." 190 Ct.Cl. 858, 422 F.2d 874, 878 (1970) (citation omitted).

However, the evidence here was sufficient to support a conclusion that there was an expectation of confidentiality between Dr. Palmaz and each of the two commercial entities. While the Shiley legal agreement executed before development discussions disclaimed a confidentiality requirement, Dr. Palmaz testified that he requested confidentiality during subsequent discussions and was "surprise[d]" when he was shown the language of the Shiley agreement. J.A. at 8517; *id.* at 19,354. There is no suggestion that the request for confidentiality was not, in fact, honored. Dr. Palmaz confirmed that the entities kept their copies of the monograph confidential, whether or not they were legally obligated to do so. J.A. at 8502. The district court noted that "there is no evidence that [the commercial entities] would have distributed, or in fact did distribute, the 1980 Monograph

outside of the company." *Cordis Corp. v. Boston Scientific Corp.*, Civ. No. 03-027-SLR, 2005 WL 1331172, at *4 (D.Del. June 3, 2005). There was no showing that similar documents in the past became available to the public as a result of disclosure by these or similar commercial entities, that these or similar commercial entities typically would make the existence of such documents known and would honor requests for public access, or that these or similar commercial entities had an incentive to make the document available, etc. The mere fact that there was no legal obligation of confidentiality–all that was shown here–is not in and of itself sufficient to show that Dr. Palmaz's expectation of confidentiality was not reasonable.[13]

We affirm the district court's holding that Dr. Palmaz's 1980 and 1983 monographs were not prior art printed publications under § 102(b), and we affirm the district court's grant of Cordis's summary judgment motion that the claims of the '762 patent are not invalidated by the Palmaz monographs.

### B. *Anticipation*

Boston Scientific argues that the jury erred in finding that claim 2 of the '406 patent is not invalid, and

13. Boston Scientific asserted that the district court improperly did not allow it to argue that the monographs were prior art in light of the result of a different litigation involving the '762 patent. We do not need to reach the question of whether the earlier determination that the '762 patent was "valid" precluded further litigation of the validity determination in this case.

that the district court erred in not granting judgment as a matter of law on grounds of anticipation. Anticipation is a question of fact; we review the jury's verdict for substantial evidence. *Voda v. Cordis Corp.*, 536 F.3d 1311, 1321 (Fed. Cir. 2008).

Boston Scientific's theory is that Cordis's '762 patent anticipates claim 2 of Cordis's '406 patent. The parties agree that the '762 patent includes all elements of claim 2 of the '406 patent, save for the functional language in claim 1 of the '406 patent (on which claim 2 of the '406 patent depends). This functional language states, "such that the links and bands define an expandable structure having *axial flexibility* in an unexpanded configuration." '406 patent col.5 ll.35-39 (emphases added).[14]

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14. Claims 1 and 2 of the '406 patent state:

> 1. A stent having first and second ends with an intermediate section there-between, and a longitudinal axis, comprising:
>
> a plurality of longitudinally disposed bands, wherein each band defines a generally continuous *wave* having a spatial frequency along a line segment parallel to the longitudinal axis; and
>
> a plurality of links for maintaining the bands in a tubular structure, wherein the links are so disposed that any single circumferential path formed by the links is discontinuous;

(Cont'd)

Boston Scientific argues that this "such that" claim language cannot operate as a claim limitation to distinguish the '406 patent over the prior art. Contrary to Boston Scientific's argument, we have held that functional language can be a claim limitation. *See Microprocessor Enhancement Corp. v. Tex. Instruments Inc.*, 520 F.3d 1367, 1375 (Fed. Cir. 2008). We conclude that the jury could properly find that the "such that" claim language is a limitation of claim 1 of the '406 patent that barred a finding of anticipation.

Boston Scientific alternatively argues that even if the "such that" functional language limits claim 2 to stents "having axial flexibility," the evidence demonstrated that the '762 patent disclosed such axial flexibility. The district court, citing both the testimony of Boston Scientific's expert Dr. Moore and the presumption of a patent's validity, held that the evidence presented was sufficient for the jury to find that the '762 patent did not anticipate claim 2 of the '406 patent. The district court properly concluded that substantial evidence supported the jury's verdict that claim 2 of Cordis's '406 patent was not invalid.

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(Cont'd)

> *such that* the links and bands define an expandable structure having *axial flexibility* in an unexpanded configuration.
>
> 2. A stent according to claim 1, wherein each link is axially displaced from any circumferentially adjacent link.

'406 patent col.5 ll.26-41 (emphases added).

*Appendix A*

We affirm the district court's denial of Boston Scientific's motion for judgment as a matter of law that claim 2 of the '406 patent is anticipated and invalid.

C. "*Thin-walled*"

Boston Scientific argues that the jury erred in finding that Boston Scientific's Express and Taxus Express stents literally infringe claim 23 of the '762 patent, and in finding that Boston Scientific induced literal infringement of claim 1 of the '762 patent with respect to these stents.[15] Claim 23 of the '762 patent

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15. Claims 1, 13, and 23 of the '762 patent state:

1. A method for implanting a prosthesis within a body passageway comprising the steps of:

utilizing a *thin-walled*, tubular member as the prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed *substantially parallel* to the longitudinal axis of the tubular member;

disposing the prosthesis upon a catheter;

inserting the prosthesis and catheter within the body passageway by catheterization of said body passageway; and

expanding and deforming the prosthesis at a desired location within the body passageway by expanding a portion of the catheter associated with the prosthesis to force the prosthesis radially outwardly into

(Cont'd)

*Appendix A*

(Cont'd)

contact with the body passageway, the prosthesis being deformed beyond its elastic limit.

13. An expandable intraluminal vascular graft, comprising:

a *thin-walled* tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed *substantially parallel* to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

'762 patent col. 10 l.6-col. 11 l.9; col. 11 l.62-col. 12 l.15; col. 12 ll.55-60 (emphases added).

depends from claim 13. '762 patent col.12 ll.55-60. Boston Scientific also argues that the district court erred in denying its motion for judgment as a matter of law of noninfringement under the "thin-walled" limitation of claim 1 and claim 13.

First, Boston Scientific argues that the district court construed the term "thin-walled" improperly. The district court construed "thin-walled" in claim 1 and claim 13 of the '762 patent as "the wall of the tubular member must have little extent from one surface to its opposite at both its first and second diameters." *Claim Construction*, 2005 WL 1322966, at *2. The district court's claim construction was proper, and the district court was not obligated, as Boston Scientific urges, to construe "thin-walled" to exclude stent walls whose struts are thicker than they are wide.

Second, Boston Scientific complains that the district court refused to allow Boston Scientific to argue the prosecution history of the '762 patent to the jury, and that the district court's exclusion of this argument prejudiced Boston Scientific's noninfringement case. Boston Scientific had sought to use the prosecution history of the '762 patent to show that Cordis had admitted that stents whose thicknesses were within a particular numerical range were not "thin-walled."[16]

16. When affirming the district court's denial of Cordis's preliminary injunction motion in this case, we found no error in the district court's conclusion that the prosecution history did not limit "thin-walled" to "thicknesses no greater than 0.0045 inches." *Cordis Corp.*, 99 Fed.Appx. at 933.

In effect, Boston Scientific sought to argue claim construction to the jury. We have held that it is improper to argue claim construction to the jury because the "risk of confusing the jury is high when experts opine on claim construction." *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172-73 (Fed.Cir.2005); *see Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 n. 6 (Fed.Cir.2008). The district court thus properly excluded Boston Scientific's claim construction argument before the jury, and properly held that its exclusion of this argument did not entitle Boston Scientific to a new trial.

Third, Boston Scientific argues that even under the district court's claim construction, Cordis did not present sufficient evidence that the Express and Taxus Express stents meet the "thin-walled" limitations of claim 1 and claim 13 (on which claim 23 depends). The district court cited testimony by Cordis's expert Dr. Buller describing how the Express and Taxus Express stents meet the "thin-walled" limitation of claims 1 and 23 under the district court's construction of this limitation. *Memorandum Opinion*, 2006 WL 1305227, at *12. We conclude that the district court properly found that Cordis presented substantial evidence to support the jury's infringement verdict.

We affirm the district court's denial of Boston Scientific's motion for judgment as a matter of law that the Express and Taxus Express stents do not infringe claims 1 and 23 of the '762 patent under the "thin-walled" limitation of these claims.

*Appendix A*

D. "*Substantially parallel*"

Boston Scientific argues that the jury erred in finding that Boston Scientific's Liberté stent infringes claims 1 and 23 of the '762 patent, and that the district court erred in denying Boston Scientific's motion for judgment as a matter of law of noninfringement under the "substantially parallel" limitations of claim 1 and claim 13 (on which claim 23 depends). Both claim 1 and claim 13 describe stents whose slots (spaces or openings within a stent's lattice design) are "disposed *substantially parallel* to the longitudinal axis" of the stent. '762 patent col. 10 l.61-col.11 l.9; col. 11 l.62-col. 12 l.15 (emphasis added).

Boston Scientific first contends that the district court erred by not construing the term "parallel" in claim 1 and claim 13 of the '762 patent. This argument was not timely raised before the district court and has been waived. *Conoco*, 460 F.3d at 1359.

Next, Boston Scientific argues that Cordis did not present substantial evidence that the Libert é stent meets the "substantially parallel" limitation in claims 1 and 23. Boston Scientific asserts that the Libert é stent's banana-shaped slots are not substantially parallel to the stent's longitudinal axis. The district court cited testimony of both parties' experts to support its finding that Cordis provided sufficient evidence to support the jury's infringement verdict under the "substantially parallel" limitation. *Memorandum Opinion*, 2006 WL 1305227, at *10. We conclude that substantial evidence supported the jury's verdict.

Boston Scientific further asserts that the district court's exclusion of the deposition testimony about the Libert é stent by Dr. Palmaz, the inventor of the '762 patent, warrants a new trial. Dr. Palmaz testified during a deposition that the slots of the Libert é stent "deviate from the longitudinal axis" of the stent. J.A. at 11,520. The district court excluded this testimony, finding that Dr. Palmaz was not an expert on the Liberté stent and that his testimony did not provide relevant evidence of infringement and created a risk of prejudice. *Memorandum Opinion*, 2006 WL 1305227, at *14. Boston Scientific argues that this testimony of Dr. Palmaz was important in defining the meaning of the claim term "substantially parallel" and in rebutting Cordis's evidence that the Libert é stent infringed claims 1 and 23 of the '762 patent. As noted earlier, claim construction cannot be argued to the jury. *CytoLogix Corp.*, 424 F.3d at 1172-73; *see also Sundance*, 550 F.3d at 1364 n. 6. "[I]nventor testimony as to the inventor's subjective intent is irrelevant to the issue of claim construction," and as the inventor of the '762 patent, Dr. Palmaz also had no special expertise regarding the alleged infringement of the patent by the Libert é stent. *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346-47 (Fed.Cir.2008); *see also Air Turbine Tech., Inc. v. Atlas Copco AB*, 410 F.3d 701, 714 (Fed.Cir.2005). The district court's exclusion of the Libert é stent portion of Dr. Palmaz's deposition testimony was within its discretion.

We affirm the district court's denial of Boston Scientific's motion for judgment as a matter of law or a

new trial that the Libert é stent does not infringe claims 1 and 23 of the '762 patent under the "substantially parallel" limitation of these claims.

## E. *"Wave"*

Boston Scientific contends that the jury erred in finding that the Libert é stent infringes claim 2 of the '406 patent, and that the district court erred in denying Boston Scientific's motion for judgment as a matter of law of noninfringement. Claim 2 of the '406 patent depends from claim 1. '406 patent col.5 ll.39-41. The parties agree that the Libert é stent infringes all limitations of claim 2, except the limitation in claim 1 (on which claim 2 depends) describing "a plurality of longitudinally disposed bands, wherein each band defines a generally continuous *wave* having a spatial frequency along a line segment parallel to the longitudinal axis." '406 patent col.5 ll.29-32 (emphasis added).

First, Boston Scientific argues that the district court improperly refused to construe the term "wave" in claim 1. In fact, the district court did construe the claim language "longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis" as "the stent has multiple elongated surfaces that run parallel to the stent's long axis, each of these surfaces having the undulating appearance of a continuous wave," though it did not separately construe the term "wave." *Construction*, 2005 WL 1322966, at *1.

As the district court pointed out, Boston Scientific did not suggest until after the close of the trial that the district court was required to construe the term "wave" in any other respect. *Memorandum Opinion*, 2006 WL 1305227, at *6. Under *Conoco*, this argument thus was not timely raised before the district court and has been waived. 460 F.3d at 1359.

Alternatively, Boston Scientific argues that even under the district court's claim construction, the evidence did not sufficiently support the jury's infringement verdict. This contention is without merit. The district court cited testimony by Cordis's expert Dr. Buller applying the court's claim construction and describing how the Libert é stent meets the limitations of claim 2 of the '406 patent. *Memorandum Opinion*, 2006 WL 1305227, at *4. We conclude that Cordis presented substantial evidence to support the jury's infringement verdict.

We affirm the district court's denial of Boston Scientific's motion for judgment as a matter of law that the Libert é stent does not infringe claim 2 of the '406 patent.

### F. *Dismissal without prejudice*

The district court granted Boston Scientific's motion for judgment as a matter of law that its Taxus Libert é stent (not to be confused with its Libert é stent or its Taxus Express stent) did not infringe the asserted claims of Cordis's '762 and '406 patents. The district

court held that it did not have jurisdiction to consider infringement claims relating to the Taxus Libert é stent because that stent had "no nexus to the United States." *Memorandum Opinion*, 2006 WL 1305227, at *24.

However, Boston Scientific argues that the district court erred in dismissing Cordis's infringement claims against the Taxus Libert é stent without prejudice, rather than with prejudice, and asserts that Cordis failed to prove that the Taxus Libert é stent infringed the asserted claims of the '762 and '406 patents. Cordis asserts that it did not present evidence at trial that the Taxus Libert é stent infringed the asserted claims of the '762 and '406 patents under 35 U.S.C. § 271(f) because it believed such evidence related only to damages rather than to infringement liability.[17]

"Congress has not clearly stated in 35 U.S.C. § 271 or in any other statute that § 271's requirement that the infringing act happen within the United States is a threshold jurisdictional requirement as opposed to an element of the claim." *Litecubes, LLC v. N. Light Prods., Inc.*, 523 F.3d 1353, 1363 (Fed. Cir. 2008), *cert. denied* sub nom. *GlowProducts.com v. Litecubes, LLC*, 129 S.Ct. 578 (2008). Thus, the question of whether the Taxus Libert é stent had a nexus to the United States was an element of Cordis's liability claims, rather than a

17. Cordis argues that the Taxus Libert é stent has the same structure as the Libert é stent. We see no error in the district court's determination that the Taxus Liberté stent and the Libert é stent are different products.

jurisdictional requirement. Because "a failure to prove the allegations alleged in a complaint requires a decision on the merits, not a dismissal for lack of subject matter jurisdiction," *id.* at 1361, the district court's dismissal of Cordis's infringement claims regarding the Taxus Libert é stent should have been with prejudice.

We reverse the district court's dismissal without prejudice of Cordis's claims that the Taxus Libert é stent infringed the asserted claims of the '762 and '406 patents, and remand with instructions to dismiss the claims with prejudice.

III

We affirm the district court's judgment in all respects save one. We reverse the district court's dismissal without prejudice of Cordis's claims that the Taxus Libert é stent infringed the asserted claims of the '762 and '406 patents, and remand with instructions to dismiss the claims with prejudice.

AFFIRMED-IN-PART, REVERSED-IN-PART, REMANDED

COSTS

No costs.

## APPENDIX B — ORDER OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED JUNE 3, 2005

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

Civ. No. 03-027-SLR

CORDIS CORPORATION,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
and SCIMED LIFE SYSTEMS, INC.,

Defendants.

**ORDER**

At Wilmington this 3d day of June, 2005, consistent with the memorandum opinion issued this same date;

IT IS ORDERED that:

1. BSC's motion for summary judgment that the asserted claims of the '762 patent are invalid (D.I. 229) is denied.

2. Cordis' motion for summary judgment that the asserted claims of the '762 patent are not invalid (D.I. 218) is granted as to the asserted claims being invalidated by the Palmaz Monographs.

*Appendix B*

3. Cordis' motion for summary judgment that the asserted claims of the '762 patent are not invalid (D.I. 218) is denied as to the asserted claims being obvious or not enabled.

s/ Sue L. Robinson
Sue L. Robinson
United States District Judge

## APPENDIX C — MEMORANDUM OPINION OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE DATED JUNE 3, 2005

## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Civ. No. 03-027-SLR

CORDIS CORPORATION,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants.

## MEMORANDUM OPINION

Dated: June 3, 2005
Wilmington, Delaware

Sue L. Robinson
ROBINSON, Chief Judge

### I. INTRODUCTION

On January 13, 2003, plaintiff Cordis Corporation ("Cordis") filed this patent infringement action against defendants Boston Scientific Corporation and Scimed

Life Systems, Incorporated (collectively "BSC") alleging infringement of U.S. Patent No. 4,739,762 ("the '762 patent") by BSC's EXPRESS and TAXUS EXPRESS stents. (D.I. 1) On March 5, 2003, BSC answered and counterclaimed against Cordis, alleging that some of Cordis' stents infringed U.S. Patent No. 5,922,021 ("the '021 patent"). (D.I. 26) On August 2, 2004, Cordis filed an amended complaint alleging BSC's LIBERTE stent infringed the '762 patent and U.S. Patent No. 5,895,406 ("the '406 patent"). (D.I. 161) On August 18, 2004, BSC answered the amended complaint. (D.I. 163)

This court has jurisdiction pursuant to 28 U.S.C. § 1331. Pending before the court are the parties' motions for summary judgment with respect to the validity of the '762 patent. (D.I. 218, 229)

## II. BACKGROUND

### A. The Palmaz Monographs

In 1980, Dr. Palmaz, the inventor of the '762 patent, wrote an "untitled, unpublished document relating to a balloon expandable intraluminal graft" ("the 1980 Monograph") to distribute to colleagues.[1] (D.I. 231, Ex.

1. The 1980 Monograph described the development of angioplasty and the drawbacks of the procedure. (D.I. 231, Ex. 3) Specifically, Dr. Palmaz noted that angioplasty worked by stretching the vessel and one of the problems with the procedure was determining an adequate amount of pressure to use that would stretch the vessel without rupturing it. (*Id.*) The (Cont'd)

1 at ¶ 3, Ex. 2 at 22-23, Ex. 12 at 320; D.I. 260, Ex. 1 at 870) At the time, he worked at the VA Medical Center in Martinez, California. (D.I. 231, Ex. 1 at ¶ 3) Dr. Palmaz gave a copy of the 1980 Monograph to faculty members at the VA Medical Center during a presentation he did for his supervisors at the Center, including Dr. Stanley Carson, Dr. Stanley Reich and Dr. Reuter.[2] (D.I. 231, Ex. 6 at 317-18, Ex. 7 at 2812, Ex. 8 at 17, 59, 202; D.I. 260, Ex. 2 at 202) Two radiologists, various department staff members and other people Dr. Palmaz did not know were at his presentation. (*Id.*)

For the next three years, Dr. Palmaz met with several companies "to interest them in developing and funding research for [his] intraluminal graft." (D.I. 231, Ex. 1 at ¶ 5) Dr. Carson arranged a meeting between Dr. Palmaz and Vascor, a vascular device company, at which Dr. Palmaz gave Vascor a copy of the 1980 Monograph. (D.I. 231, Ex. 6 at 318-19, Ex. 8 at 202-04,

(Cont'd)

1980 Monograph proposes placing an "intraluminal tubular structure" into a vessel as an alternative to angioplasty. (*Id.*) The "wire mesh" tube could expand and resist the "recoil" of the vessel wall. (*Id.*) The tube would be "mounted in the collapsed state over a modified . . . balloon catheter" for delivery into the vessel. (*Id.*) The tube would be made of "modern non-thrombogenic vascular prosthetic materials" and have a "fenestrated or a corrugated external surface" to prevent displacement of the tube. (*Id.*)

2. Dr. Palmaz was a resident at the Center. (D.I. 260, Ex. 1 at 873) The 1980 Monograph did not contain a cover page or have Dr. Palmaz's name on it. (D.I. 260, Ex. 1 at 870)

Ex. 12 at 326) Vascor was interested in Dr. Palmaz's invention and extended to Dr. Palmaz an agreement letter stating that they would acknowledge him and Dr. Carson as the "originators" of the invention. (D.I. 231, Ex. 6 at 320, Ex. 8 at 205-07) The agreement also stated that Vascor was not committed to keeping the idea or material submitted a secret, however, Dr. Palmaz thought the submission would be kept confidential.[3] (D.I. 231, Ex. 6 at 396; D.I. 260, Ex. 3 at 274-75) Vascor, however, did not develop Dr. Palmaz's stent. (D.I. 231, Ex. 6 at 321-22, Ex. 12 at 327) Sometime after extending to Dr. Palmaz the letter agreement, Vascor indicated it was not interested in his invention. (D.I. 231, Ex. 6 at 321-22)

Next, Dr. Palmaz approached Shiley Corporation, also a vascular device company, about developing his stent. (D.I. 231, Ex. 6 at 322, Ex. 12 at 327) Dr. Palmaz presented his 1980 Monograph to Shiley. (*Id.*) After Dr. Palmaz executed an agreement, in which he agreed Shiley did not have to keep his invention a secret,[4] Shiley agreed to take a look at Dr. Palmaz's work but, ultimately, decided not to develop Dr. Palmaz's invention.

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3. According to Dr. Palmaz, he understood that talking with companies, like Vascor, "was supposed to be done in privacy, and there was an understanding that they would keep your idea confidential. Otherwise, it would be totally unreasonable to make that kind of disclosure to them." (D.I. 260, Ex. 3 at 275)

4. Dr. Palmaz stated that despite this agreement he thought the disclosure of the 1980 Monograph to Shiley would be kept confidential. (D.I. 231, Ex. 11 at 273, 275-77)

(D.I. 231, Ex. 6 at 323, Ex. 11 at 273, Ex. 12 at 329, Ex. 19)

Shortly thereafter, Dr. Palmaz presented the 1980 Monograph to Cook, Incorporated, a company involved in vascular devices. (D.I. 231, Ex. 6 at 324, Ex. 2 at 329) Cook was not interested, but directed Dr. Palmaz to Werner Schultz, a retired biotechnology technician from Stanford University. (D.I. 231, Ex. 6 at 324, Ex. 8 at 93-94, Ex. 12 at 30-32; D.I. 260, Ex. 2 at 2) Dr. Palmaz subsequently met with Mr. Schultz and gave him a copy of the 1980 Monograph. (D.I. 231, Ex. 6 at 324-26, Ex. 8 at 95-96; D.I. 260, Ex. 2 at 96) Mr. Shultz gave Dr. Palmaz ideas about how to improve the invention, which Dr. Palmaz incorporated into a revision of the 1980 Monograph. (D.I. 231, Ex. 6 at 326)

On May 18, 1983, Dr. Palmaz revised the 1980 Monograph into an unpublished paper entitled, "Research Project – Expandable Vascular Endoprosthesis" ("the 1983 Monograph"). (D.I. 231, Ex. 1 at ¶ 6) Dr. Palmaz sent a copy of the revision to Mr. Schultz.[5] (D.I. 231, Ex. 6 at 327) At this time, Dr. Palmaz was still at the VA Medical Center in California, but was speaking with the University of Texas Health Science Center in San Antonio, Texas ("UTHSCSA") about future employment. (D.I. 231, Ex. 1 at ¶¶ 6, 7, 8) Dr. Reuter, a collegue working at UTHSCSA who had worked at the VA Medical Center in California, was Dr.

5. Mr. Schultz died before Dr. Palmaz got to speak with him about the 1983 Monograph. (D.I. 231, Ex. 6 at 327)

Palmaz's contact at UTHSCSA. (D.I. 231, Ex. 1 at ¶ 8) Dr. Reuter was given a copy of the 1983 Monograph, and had also received a copy of the 1980 Monograph. (D.I. 231, Ex. 1 at ¶¶ 8, 10) Once Dr. Palmaz accepted a position at UTHSCSA, Dr. Reuter gave a copy of the 1983 Monograph to Joseph E. Peters, Jr., an employee at UTHSCSA, so that Mr. Peters could equip an animal laboratory for Dr. Palmaz. (D.I. 231, Ex. 1 at ¶ 10; Ex. 2 at 44)

**B. The '762 Patent**

The '762 patent has been the subject of substantial litigation in this court. In 1998, Cordis sued BSC alleging infringement of the '762 patent by BSC's NIR stent. *See Cordis Corp. v. Boston Scientific Corp.*, 97-550-SLR (D. Del.). During discovery in the 97-550 case, BSC took depositions of Dr. Palmaz, the inventor of the '762 patent, where he was asked about his 1980 and 1983 Monographs ("Palmaz Monographs") which describe his balloon expandable stent. (D.I. 220, Ex. 2) According to the 97-550 pretrial order, BSC intended to assert a statutory bar defense. (97-550-SLR, D.I. 882, Ex. 5 at 3, 884, Ex. 11 at DTXB 69) A jury trial on BSC's alleged infringement of the '762 patent was held in 2000, during which BSC chose not to present an invalidity defense although BSC did examine Dr. Palmaz with respect to the Palmaz Monographs. (D.I. 220, Ex. 3)

Upon appeal, the Federal Circuit affirmed in part, reversed in part and remanded the case. *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352 (Fed. Cir. 2003).

*Appendix C*

Consistent with the Federal Circuit's decision, construction of two limitations, "slots formed therein" and "substantially uniform thickness," was revised. In a May 14, 2004 order, the court allowed BSC to submit supplemental reports on the validity of claim 23 of the '762 patent in light of the revised claim construction. (97-550-SLR, D.I. 1228) During the pretrial for the 97-550 case, BSC attempted to assert a statutory bar defense based on the Palmaz Monographs, which defense was not included in its supplemental reports. (D.I. 263, Ex. B at 9) According to BSC, there was newly discovered evidence that led them to believe the '762 patent was invalid due to the Palmaz Monographs.[6] (*Id.*) After hearing BSC's and Cordis' arguments on the issue, the court determined that a new invalidity defense was outside the scope of the remanded 97-550 case. (*Id.* at 14) The court did not preclude BSC from raising the defense at bar. (*Id.* at 15) A second jury trial on the '762 patent was held in March 2005. The jury found that the NIR stent infringed the '762 patent and that the patent was valid. (97-550-SLR, D.I. 1366)

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6. BSC fails to assert any witness or piece of evidence that was not available to it prior to the 97-550 trial. (*Id.*; *see also* D.I. 231) Likewise, it fails to cite to any deposition testimony that was different than that given by witnesses in the 97-550 case. (D.I. 263 at 7-8) BSC cites one 2004 case in support of its statutory bar defense, but uses it as in accord with a case from 2002 and 1985. (D.I. 231 at 10, 13) Therefore, the case did not change the law to the extent that a statutory bar defense would suddenly become available when it was not before.

In this case, where Cordis contends that BSC's EXPRESS, TAXUS and LIBERTE stents infringe the '762 patent, BSC has again asserted a statutory bar defense, arguing the '762 patent is invalid because the Palmaz Monographs were publicly available more than one year prior to the '762 application date.

## III. STANDARD OF REVIEW

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pa. Coal Ass'n v. Babbitt*, 63 F.3d

231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

## IV. DISCUSSION

### A. BSC's Motion For Summary Judgment That The Asserted Claims Of The '762 Patent Are Invalid

Under 35 U.S.C. § 102(b), "[a] person shall be entitled to a patent unless the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." BSC argues that the '762 patent is invalid as anticipated by the Palmaz Monographs, which, according to BSC, were printed publications that were available more than a year prior to Dr. Palmaz filing the application that gave rise to the '762 patent. Cordis argues that the Palmaz Monographs are not printed publications because they were not publicly accessible.

*Appendix C*

"The statutory phrase 'printed publication' has been interpreted to mean that, before the critical date, the reference must have been sufficiently accessible to the public interested in the art; dissemination and public accessibility are the keys to the legal determination whether a prior art reference was 'published.'"[7] *In re Cronyn*, 890 F.2d 897, 1160 (Fed. Cir. 1986). Whether something is a "printed publication" is determined on a case by case basis, requiring inquiry into the facts and circumstances of the references' disclosure to the public. *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004).

A court should also consider whether or not the "printed publication" was the subject of confidentiality agreements or whether the disclosing party had "a reasonable expectation that the information [would] not be copied." *In re Klopfenstein*, 380 F.3d at 1351. "Professional or behavioral norms [that] entitle a party to a reasonable expectation that the information displayed will not be copied" can also be evidence that something is not a "printed publication." *Id.* On the other hand, "evidence of business practice that was sufficient to prove [a document] was widely available and accessible to the interested public" can be sufficient to prove that the document was publicly accessible. *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988).

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7. The relevant "public" consists of those individuals who would be interested in the invention, or the relevant art. *Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc.*, 291 F.3d 1317, 1324 (Fed. Cir. 2002).

*Appendix C*

Dr. Palmaz distributed the 1980 Monograph as a handout to his colleagues at the VA Medical Center during a presentation. There is no evidence that this was a public presentation, analogous to a presentation at a conference. *See, e.g., Mass. Inst. of Tech. v. AB Fortia*, 774 F.2d 1104, 1108-09 (Fed. Cir. 1985). The presentation and distribution was of an internal character, and there is no evidence that those of interest could have found the document, much less gained access to it. *See* Donald S. Chisum, Chisum On Patents § 3.04[2] (2002). There is no evidence that Dr. Palmaz's intent was anything other than getting feedback to further his research, nor evidence that he expected anything less than full confidentiality from these colleagues.

Dr. Palmaz also distributed the 1980 Monograph to three companies in an effort to attract funding and a co-developer. In *Garrett Corp. v. United States*, 422 F.2d 874, 878 (Ct. Cl. 1970), the court stated that "distribution to commercial companies without restriction on use clearly" constitutes publication. In that case, 80 copies of an unclassified, unrestricted government report were distributed to government agencies and private companies. *Id.* The report was made available to government contractors upon request free of charge. *Id.* In this case, there is no evidence that either Vascor, Shiley or Cook would have distributed, or in fact did distribute, the 1980 Monograph outside of the company. Furthermore, Dr. Palmaz has testified that he expected the companies to keep the monograph confidential, as it was his perception that confidentiality was an industry practice. Absent some indication that these companies

would have freely distributed the monograph, the court declines to find that the monograph was accessible to those interested, solely because it was given to the companies.

The 1983 Monograph was given to three people, two of whom were employed at UTHSCSA. Dr. Palmaz's intent again was to further his research and facilitate his employment at UTHSCSA, neither of which evidences an intent to make his invention publicly accessible. There is no evidence that Dr. Palmaz's disclosure made the monograph accessible to anyone other than those at UTHSCSA or Mr. Schultz. Nor is it evident that anyone at UTHSCSA could access the monograph, as opposed to limited access by Dr. Reuter and Mr. Peters. Like his distribution at the VA Medical Center, Dr. Palmaz's distribution to UTHSCSA was an internal disclosure. Even assuming that those of interest could have found out about the 1983 Monograph, there is no indication that UTHSCSA would have freely distributed the 1983 Monograph. Therefore, BSC's motion for summary judgment is denied, as the Palmaz Monographs are not prior art under § 102(b).

### B. Cordis' Motion For Summary Judgment That The Asserted Claims Of The '762 Patent Are Not Invalid

Assuming for the purposes of argument that the Palmaz Monographs are prior art, Cordis argues that BSC is precluded from asserting them as invalidating

prior art in this case.[8] Specifically, Cordis contends that issue preclusion prevents BSC from asserting its invalidity defense, because the jury in the 97-550 case found the '762 patent to be valid.[9] BSC contends that the issues and claims in the present case are not the same as those litigated in the 97-550 case.[10]

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8. Cordis also argues that BSC's experts are applying the wrong invalidity standard in their discussions of enablement and written description. After reviewing the expert reports of Dr. Moore, Dr. Goldberg and Dr. Benet, the court concludes that these experts are not applying an incorrect standard. The experts address whether or not the '762 patent enables and/or describes a drug-eluting stent. To the extent that Cordis claims that drug-eluting stents are covered by the '762 patent, the experts' analysis is appropriate.

9. Cordis also argues that claim preclusion prevents BSC from bringing an invalidity defense. However, the Federal Circuit has stated that an assertion of invalidity by an alleged infringer is not a "claim" but a defense to the claim of infringement. *Foster v. Hallco Manufacturing Co., Inc.*, 947 F.2d 469, 479 (Fed. Cir. 1991). "An essential fact of a patent infringement claim is the structure of the device . . . at issue"; therefore, for claim preclusion to apply, the accused devices must be "essentially the same." *Id.*; *see also* Robert L. Harmon, Patents and the Federal Circuit 962 (4th ed. 1999). In this case, Cordis has not proven that the NIR stent is the same as the EXPRESS, TAXUS or LIBERTE stents.

10. BSC also argues that Cordis waived its defense because it did not plead issue or claim preclusion in its answer to BSC's counter-claims as required by Federal Rule of Civil Procedure 8(c). The Third Circuit has recognized exceptions to Rule 8(c) when a defendant "'raised the issue at a pragmatically sufficient

(Cont'd)

*Appendix C*

The party invoking issue preclusion must demonstrate that four factors are met: "'(1) the issue sought to be precluded [is] the same as that involved in the prior action; 2) that issue [was] actually litigated; 3) it [was] determined by a final and valid judgment; and 4) the determination was essential to the prior judgment.'" *Burlington Northern Railroad Co. v. Hyundai Merchant Marine Co., Ltd.*, 63 F.3d 1227, 1231 (3d Cir. 1995) (quoting *In re Graham*, 973 F.2d 1089, 1097 (3d Cir. 1992)).

Even if all the criteria are satisfied, application of the doctrine is "subject to [an] overriding fairness determination by the trial judge." *Burlington*, 63 F.3d at 1231. The party resisting issue preclusion should be "permitted to demonstrate . . . that he did not have 'a fair opportunity procedurally, substantively and evidentially to pursue his claim the first time.'" *Blonder-Tongue Laboratories, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 333 (1971) (quoting *Eisel v. Columbia Packing Co.*, 181 F. Supp. 298, 301 (D. Mass. 1960)).

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(Cont'd)

time, and [the plaintiff] was not prejudiced in its ability to respond.'" *Charpentier v. Godsil*, 937 F.2d 859, 864 (3d Cir. 1991) (quoting *Lucas v. United States*, 807 F.2d 414, 418 (5th Cir. 1986). The court finds that BSC has not been prejudiced by Cordis' failure to plead preclusion in its answer because Cordis alerted BSC to its intent to move to preclude BSC's arguments at the pretrial for the 97-550 case. (D.I. 263, Ex. B at 11) BSC had an opportunity to respond both at the pretrial and while briefing dispositive motions in this case. (*Id.* at 11-12)

*Appendix C*

**1. Same Issue**

The Supreme Court has recognized that a finding of invalidity in one suit can be the basis for issue preclusion in a subsequent suit. *See Blonder-Tongue Laboratories, Inc.*, 402 U.S. 313 (1970). BSC argues that validity in this case does not present the same issue because its statutory bar defense was not in the 97-550 case. BSC, however, was a party to the 97-550 case and, as such, had the opportunity to bring its statutory bar defense. BSC cannot now avoid preclusion by bringing forth evidence that was available to it prior to the first 97-550 trial. *See Stevenson v. Sears, Roebuck & Co.*, 713 F.2d 705, 711 n.4 (Fed. Cir. 1983); Restatement (Second) of Judgments § 27 cmt. c (1982).

Under federal law, each claim defines a separate invention and the validity of dependent claims is not affected by the validity of the claims from which they depend. See 35 U.S.C. § 282 (2004); *Honeywell Int'l. Inc. v. Hamilton Sunstrand Corp.*, 370 F.3d 1131, 1148 (2004). Nevertheless, finding an independent claim valid necessarily means the dependent claims are valid. *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1107-08 (Fed. Cir. 1987). Therefore, the finding of validity in the 97-550 case will have a preclusive effect with respect to claim 23 and the claims that depend from it. However, the validity of claims 1, 9 and 12 are a different issue than that litigated in the 97-550 case and BSC is not precluded from asserting their invalidity, consistent with the other pretrial decisions of the court.

**2. Issue Was Actually Litigated**

The validity of claim 23 of the '762 patent was litigated in the 97-550-SLR case. (97-550-SLR, D.I. 1366)

**3. Valid And Final Judgment**

Judgment against BSC was entered on March 31, 2005. (D.I. 1375) Although the court has not decided the post-trial motions, even before an "end judgment" a court may regard a judgment as final if the decision was "adequately deliberated and firm" or "procedurally firm." *Id.* at cmt. g. There are a number of factors to be considered in this regard: (1) whether the prior decision was adequately deliberated and firm; (2) whether the parties were fully heard; and (3) whether the decision is subject to appeal or was in fact appealed. *Greenleaf v. Garlock, Inc.*, 174 F.3d 352, 358 (3d Cir. 1999).[11]

In this case, the parties were fully heard on the issue of invalidity, as there have been two jury trials, an appeal, and countless briefs on the issue. BSC was represented by counsel throughout these proceedings, counsel that fiercely contested the validity of claim 23 of the '762 patent in the second 97-550 trial. The jury's verdict was firm and reasonably deliberated; there is no indication otherwise. As such, the court concludes

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11. There is a fourth factor, i.e., "whether the court supported its decision with a reasoned opinion," that does not apply in this case because it ended with a jury verdict. *Greenleaf*, 174 F.3d at 359.

that a jury verdict is "procedurally firm" and can be considered a final judgment for issue preclusion purposes. *See Greenleaf v. Garlock, Inc.*, 174 F.3d 352, 357-59.

### 4. Determination Was Essential To The Prior Judgment

In determining the validity of the '762 patent, the jury would have had to consider whether claim 23 of the '762 patent was valid.

### 5. BSC's Opportunity To Litigate

BSC argues that it did not have an opportunity to litigate the invalidity of the '762 patent because the court prevented it from bringing its statutory bar defense on remand. The court disagrees.

In this case, BSC failed to bring its statutory bar defense in 2000 for the first 97-550 trial, even though Cordis produced the Palmaz Monographs during discovery and made Dr. Palmaz available for numerous depositions. Upon remand, the claim construction of the '762 patent changed and the scope of claim 23 changed. In May 2004, the court allowed BSC to supplement the record on the issue of invalidity in light of this new claim construction. (97-550-SLR, D.I. 1228) Expert discovery for the second 97-550 trial closed prior to the pretrial, when BSC raised its statutory bar defense. This defense could have been raised as early as 1999, as BSC had access to both the Palmaz Monographs and Dr. Palmaz.

Therefore, contrary to the court's statements at the 2005 pretrial, it is appropriate to preclude BSC's statutory bar defense in this case, given BSC's failure to timely raise the defense for either the 2000 or 2005 trials in the 97-550 case and given the absence of any newly discovered evidence in this regard. Because the requirements for issue preclusion have been satisfied, Cordis' motion for summary judgment is granted with respect to claims 19, 22 and 23.

## V. CONCLUSION

For the reasons stated, BSC's motion for summary judgment that the asserted claims of the '762 patent are invalid is denied. Cordis' motion for summary judgment that the asserted claims of the '762 patent are not invalid is granted in part and denied in part. An order consistent with this memorandum opinion shall issue.

## APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DENYING PETITION FOR REHEARING EN BANC FILED JUNE 26, 2009

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

2008-1003, -1072

CORDIS CORPORATION,

Plaintiff-Appellant,

v.

BOSTON SCIENTIFIC CORPORATION and SCIMED LIFE SYSTEMS, INC.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in case no. 03-CV-027, Judge Sue L. Robinson.

**ORDER**

A combined petition for panel rehearing and for rehearing en banc having been filed by the Cross-Appellants, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

*Appendix D*

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on July 6, 2009.

FOR THE COURT,

s/ Jan Horbaly
Jan Horbaly
Clerk

Dated: 06/26/2009